

US3552371 (Prod: Saint Louis University)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:39:31

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US3552371

Form: Participant Creation

Generated On: 26 Nov 2020 09:39:31

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:39:31

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

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:39:31

Date of Birth (MMM yyyy)	(b) (6) 1964
Age	56
Age Units	YEARS
Age (Derived)	56
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:39:31

Date of Informed Consent (<i>dd MMM yyyy</i>)	08 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☐
	Amendment 3 ☒
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:39:31

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:39:31

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:39:31

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

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:39:31

Condition	HYPOTHYROID/HASHIMOTOS
Start date (dd MMM yyyy)	UN MAY 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	MAY 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:39:31

Condition	GENERALIZED MUSCLE SORENESS
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:39:31

Condition	MITRAL VALVE REPAIR
Start date (dd MMM yyyy)	UN APR 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN APR 1995
Stop date completely unknown	False
Start Month and Year (derived)	APR 1995
Start Year (derived)	1995
Stop Month and Year (derived)	APR 1995
Stop Year (derived)	1995

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:39:31

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

US3552371

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:39:31

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:39:31

Condition	SULFA ALLERGY
Start date (dd MMM yyyy)	UN UNK 2001
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:39:31

Condition	MITRAL REGURGITATION
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN APR 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	APR 1995
Stop Year (derived)	1995

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	08 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	16:34 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 16:34
Height (<i>xxx.x</i>)	66 in
Weight (<i>xxx.x</i>)	132 lb
BMI (<i>xxx.x</i>)	21.34990 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
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 09:39:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:39:31

Date of assessment (*dd MMM yyyy*) 08 SEP 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*) UN OCT 2018

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:39:31

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:39:31

	IN HOME REPAIRS, VISITS FROM DAUGHTER AND GRANDCHILD, TRAVEL BY PLANE FOR WORK, PLAYS TENNIS, GOES TO GYM, HUSBAND WORKS OUTSIDE OF HOME, SOCIALIZING, GROCERY SHOPPING, RESTAURANT DINNING
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
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	True
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:39:31

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	08 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:39:31

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

What was the participant's randomization number? 112401

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:39:31

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 09:39:31

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	08 SEP 2020
Time of assessment (00:00-23:59)	16:34 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 16:34
Temperature (xxx.x)	98.7 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 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: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:39:31

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	08 SEP 2020
Time of assessment (00:00-23:59)	17:55 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 17:55
Temperature (xxx.x)	98.9 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:39:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:39:31

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 08 SEP 2020

What was the treatment time? (00:00-23:59) 17:25 (24 HR)

Treatment Date and Time (derived) 08 SEP 2020 17:25

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:39:31

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	08 SEP 2020
Collection time (<i>00:00-23:59</i>)	16:52 (24 HR)
Collection date and time (derived)	08 SEP 2020 16:52

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:39:31

Collection date (<i>dd MMM yyyy</i>)			08 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:55	08 SEP 2020 16:55
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:39:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:39:31

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

98.9 °F

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

Yes ☐
No ☒

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

PC Time Stamp 08 SEP 2020 17:51

PC Open Date & Time 08 SEP 2020 17:45

PC Close Date & Time 08 SEP 2020 20:15

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:39:31

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 97.1 °F

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

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

PC Time Stamp	09 SEP 2020 09:22
PC Open Date & Time	08 SEP 2020 21:10
PC Close Date & Time	09 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

09 SEP 2020 18:23

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

10 SEP 2020 13:19

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 16:45

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 15:25

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 14:28

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 21:33

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 17:52

PC Open Date & Time

08 SEP 2020 17:45

PC Close Date & Time

08 SEP 2020 20:15

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:39:31

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

09 SEP 2020 09:23

PC Open Date & Time

08 SEP 2020 21:10

PC Close Date & Time

09 SEP 2020 11:59

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 18:24

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 13:20

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 16:44

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 15:25

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 14:28

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 21:33

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:39:31

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 ☐

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:39:31

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 17:53
PC Open Date & Time	08 SEP 2020 17:45
PC Close Date & Time	08 SEP 2020 20:15

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:39:31

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 ☐

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:39:31

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 09:23
PC Open Date & Time	08 SEP 2020 21:10
PC Close Date & Time	09 SEP 2020 11:59

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:39:31

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 ☒

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:39:31

Yes ☐	
PC Time stamp	09 SEP 2020 18:24
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:39:31

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 ☒

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:39:31

Yes ☐	
PC Time stamp	10 SEP 2020 13:20
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:39:31

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 ☒

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:39:31

Yes ☐	
PC Time stamp	11 SEP 2020 16:44
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:39:31

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 ☒

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:39:31

Yes ☐	
PC Time stamp	12 SEP 2020 15:25
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:39:31

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 ☒

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:39:31

Yes ☐	
PC Time stamp	13 SEP 2020 14:29
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:39:31

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 ☒

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:39:31

Yes ☐	
PC Time stamp	14 SEP 2020 21:34
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3552371

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 15 SEP 2020 16:17

PC Open Date & Time 15 SEP 2020 12:00

PC Close Date & Time 16 SEP 2020 11:59

US3552371

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

DAY 8

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

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 15 SEP 2020 16:17

PC Open Date & Time 15 SEP 2020 12:00

PC Close Date & Time 16 SEP 2020 11:59

US3552371

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	15 SEP 2020 16:17
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3552371

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:39:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552371

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:39:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552371

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:39:31

Was Contact Attempted?

Yes ☒

No ☐

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

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552371

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:39:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552371

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:39:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552371

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:39:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552371

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:39:31

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:39:31

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	10:05 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 10:05
Temperature (xxx.x)	97.9 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	99 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:39:31

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☐
	No ☒
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 ☐
	Axillary ☐
	Other ☐
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	

US3552371

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:39:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 OCT 2020

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

US3552371

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:39:31

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 ELEVATED LIVER ENZYMES

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? _____

US3552371

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:39:31

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

13 OCT 2020

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

10:53 (24 HR)

Collection date and time (derived)

13 OCT 2020 10:53

US3552371

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:39:31

Collection date (dd MMM yyyy)			13 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:55	13 OCT 2020 10:55
Nasopharyngeal Swab 2	No		

US3552371

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:39:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552371

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:39:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552371

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:39:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552371

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:39:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552371

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:39:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552371

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:39:31

Was Contact Attempted?

Yes ☒

No ☐

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

03 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552371

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:39:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552371

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:39:31

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	10 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3552371

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

Were vital signs assessed?	Yes ☐
	No ☒
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3552371

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:39:31

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3552371

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:39:31

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	10 NOV 2020
Collection time (<i>00:00-23:59</i>)	10:44 (24 HR)
Collection date and time (derived)	10 NOV 2020 10:44

US3552371

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:39:31

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3552371

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 NOV 2020 10:38:13

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3552371

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Date and time of submission	19 NOV 2020 11:26:38
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2020 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2020 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 19:35:52
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2020 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2020 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

DAY 103

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2020 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2020 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

DAY 145

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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 ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

DAY 166

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

DAY 173

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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 ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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 ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2021 00:01

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12 APR 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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 ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

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24 MAY 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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 ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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 ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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 ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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 ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

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27 SEP 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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 ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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 ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

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17 JAN 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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 ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

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24 JAN 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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 ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

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31 JAN 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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07 FEB 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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 ☐

US3552371

Folder: New Safety Follow Up Diary (1)

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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14 FEB 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

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21 FEB 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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 ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

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28 FEB 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

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07 MAR 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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 ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

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14 MAR 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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 ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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 ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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 ☐

US3552371

Folder: New Safety Follow Up Diary (1)

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

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04 APR 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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 ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

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18 APR 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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 ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

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25 APR 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

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16 MAY 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

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23 MAY 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

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30 MAY 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

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06 JUN 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

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09 JUN 2022 00:01

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13 JUN 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

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20 JUN 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

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27 JUN 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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 ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

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04 JUL 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

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07 JUL 2022 00:01

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11 JUL 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

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18 JUL 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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 ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

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25 JUL 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

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01 AUG 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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 ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

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04 AUG 2022 00:01

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08 AUG 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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 ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

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15 AUG 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

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22 AUG 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

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29 AUG 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

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01 SEP 2022 00:01

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05 SEP 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

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08 SEP 2022 00:01

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12 SEP 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

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19 SEP 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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 ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2022 23:59

US3552371

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:39:31

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

US3552371

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:39:31

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3552371

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:39:31

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

AEID	
Adverse event	FRACTURED LEFT ANKLE
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)	16 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)	19 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	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	306 of 1751

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT FELL OFF A STEP STOOL FRACTURING HER LEFT ANKLE. TREATED IN ER AND RELEASED; NOT ADMITTED TO THE HOSPITAL.
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)	

US3552371

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

AEID	
Adverse event	ELEVATED LIVER ENZYMES
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)	16 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)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

v6.020 DTW (1102)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

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

US3552371

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

AEID	USA-US089-2020-MRNA-1273-P30 1000012
Adverse event	RIGHT KIDNEY RENAL CELL CARCINOMA
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 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	13 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	True
Hospital Admission Date (dd MMM yyyy)	12 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	13 NOV 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

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

US3552371

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

RENAL MASS FOUND ON
ULTRASOUND BY
HAPPENSTANCE AFTER ANKLE
FRACTURE. MASS FOUND TO
BE RENAL CELL CARCINOMA.
SUBJECT NOTIFIED US THAT
SHE HAD PARTIAL
NEPHRECTOMY OF HER RIGHT
KIDNEY TO REMOVE RENAL
MASS ON 12NOV. SURGERY
COMPLETED AND PATIENT HAS
RECOVERED. DISCHARGED
FROM HOSPITAL ON 13NOV.

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

US3552371

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

AEID	
Adverse event	ANXIETY
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	22 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	29 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	313 of 1751

US3552371

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

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

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:39:31

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

Yes ☒

No ☐

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

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:39:31

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

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:39:31

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN OCT 2018	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	24 SEP 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:39:31

Name of Medication	LEVOTHYROXINE
Prophylaxis	Yes ☐ No ☒
Indication	HYPOTHYROID
Dose per administration	.88
Dose unit	mg ☐ ug ☒ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:39:31

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN MAY 1995	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:39:31

Name of Medication	VITAMIN D3
Prophylaxis	Yes ☒ No ☐
Indication	HEALTH PROMOTION
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☒ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:39:31

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

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:39:31

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

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:39:31

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

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:39:31

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

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:39:31

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

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:39:31

Name of Medication	ADVIL
Prophylaxis	Yes ☐ No ☒
Indication	MUSCLE SORENESS
Dose per administration	2
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☒ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:39:31

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 1995	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	05 SEP 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:39:31

Name of Medication	PERCOCET [OXYCODONE AND ACETAMINOPHEN]
Prophylaxis	Yes ☐ No ☒
Indication	FRACTURED ANKLE
Dose per administration	5/325
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:39:31

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 21 SEP 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:39:31

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

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:39:31

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		16 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		21 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:39:31

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

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:39:31

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	21 SEP 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:39:31

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

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:39:31

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

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:39:31

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

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:39:31

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

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:39:31

Name of Medication	PERCOCET [OXYCODONE-ACETAMINOPHE N]
Prophylaxis	Yes ☐ No ☒
Indication	PARTIAL NEPHRECTOMY PAIN
Dose per administration	5-325
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:39:31

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:39:31

Name of Medication	CRYSTALLOID FLUIDS
Prophylaxis	Yes ☐ No ☒
Indication	INTRA-OP FLUIDS
Dose per administration	2500
Dose unit	mg ☐ ug ☐ mL ☒ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☒
If frequency is Other, specify	
Route of administration	CONTINUOUS Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:39:31

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	12 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)		13 NOV 2020
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:39:31

Name of Medication	MORPHINE PATIENT CONTROLLED ANALGESIC
Prophylaxis	Yes ☐ No ☒
Indication	PARTIAL NEPHRECTOMY PAIN
Dose per administration	30/3
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	MG/ML
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:39:31

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		13 NOV 2020
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

US3552371

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:39:31

[Were any concomitant procedures performed?](#)

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3552371

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 09:39:31

Procedure/Surgery date (<i>dd MMM yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
08 OCT 2020	ABDOMINAL ULTRASOUND	Adverse Event	
12 NOV 2020	PARTIAL NEPHRECTOMY OF RIGHT KIDNEY	Adverse Event	

US3552371

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:39:31

Date of dosing discontinuation (dd MMM yyyy)

13 OCT 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 #2

US3552371

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:39:31

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 ☐

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

SAEID	USA-US089-2020-MRNA-1273-P301000012
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:39:31

SAEID	USA-US089-2020-MRNA-1273-P301000012
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	20/NOV/2020 14:06
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

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:39:31

SAEID	USA-US089-2020-MRNA-1273-P301000012
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	23/NOV/2020 09:49
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

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:39:31

SAEID	USA-US089-2020-MRNA-1273-P301000012
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	24/NOV/2020 07:46
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

US3552371 (Prod: Saint Louis University)

US3552371

Form: Participant Creation

Generated On: 26 Nov 2020 09:39:31

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3552371'	RWS_ENDPOINT ENDPOINT (b) (4) 	08 Sep 2020 21:44:28

US3552371

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:39:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:30:29
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:19:12

US3552371

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:30:29
User entered '08 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 21:44:29

US3552371

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:30:29
User entered 'Clinic (Clinic)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:19:12

US3552371

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:39:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	09 Sep 2020 20:19:12

US3552371

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:30:37
User entered (b) (6) 1964'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 21:44:30

US3552371

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:39:31

[Age](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:30:37
User entered '56'	Stanley Dublin (b) (4) (b) (4)	09 Sep 2020 20:20:06

US3552371

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:39:31

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	09 Sep 2020 20:20:06

US3552371

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:39:31

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '56'	System	08 Sep 2020 21:57:22

US3552371

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:39:31

[Sex](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:30:37
User entered 'Female (F)'	Stanley Dublin (b) (4) (b) (4)	09 Sep 2020 20:20:06

US3552371

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:39:31

[Ethnicity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:30:37
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:20:06

US3552371

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:39:31

[White](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:30:37
User entered '1'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:20:06

US3552371

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:39:31

[Black](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:30:37
User entered '0'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:20:06

US3552371

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:39:31

[Asian](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:30:37
User entered '0'	Stanley Dublin (b) (4) (b) (4)	09 Sep 2020 20:20:06

US3552371

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:39:31

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:30:37
User entered '0'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:20:06

US3552371

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:39:31

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:30:37
User entered '0'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:20:06

US3552371

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:39:31

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:30:37
User entered '0'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:20:06

US3552371

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:39:31

[If race is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:30:37
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:20:06

US3552371

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:39:31

[Unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:30:37
User entered '0'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:20:06

US3552371

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:39:31

[Not reported](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:30:37
User entered '0'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:20:06

US3552371

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:44:28
DataPoint Un-verified.	Mikayla Frye (b) (4)	10 Nov 2020 17:35:12
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Mikayla Frye (b) (4)	10 Nov 2020 17:35:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:30:49
User entered '8 Sep 2020'	Cassandra Zehenny (b) (4)	08 Sep 2020 21:57:22
	(b) (4)	

US3552371

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	08 Sep 2020 21:57:22

US3552371

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered '2020'	System	08 Sep 2020 21:57:22

US3552371

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:39:31

[Protocol Version](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:30:49
User entered 'Amendment 3 (3)'	Cassandra Zehenny (b) (4) (b) (4)	08 Sep 2020 21:57:22

US3552371

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:30:49
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	08 Sep 2020 21:57:22

US3552371

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:30:49
User entered empty.	Cassandra Zehenny (b) (4)	08 Sep 2020 21:57:22
	(b) (4)	

US3552371

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:39:31

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:30:49
User entered empty.	Cassandra Zehenny (b) (4)	08 Sep 2020 21:57:22
	(b) (4)	

US3552371

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:39:31

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:30:49
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	08 Sep 2020 21:57:22

US3552371

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:39:31

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:30:49
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 21:44:29

US3552371

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:39:31

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 21:57:28

US3552371

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:31:06
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	08 Sep 2020 21:57:28

US3552371

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:39:31

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:31:15
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:22:01

US3552371

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:39:31

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
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)	09 Sep 2020 20:23:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 20:23:54
Data point term sent to Coder	System	09 Sep 2020 20:23:09
User entered 'hyperlipidemia'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:22:24

US3552371

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered 'un Oct 2018'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:22:24

US3552371

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:22:24

US3552371

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:39:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	09 Sep 2020 20:22:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	09 Sep 2020 20:22:33
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	09 Sep 2020 20:22:24
User entered 'No (N)'	Stanley Doublin (b) (4)	09 Sep 2020 20:22:24

US3552371

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:22:24

US3552371

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:39:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:22:24

US3552371

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered 'Oct 2018'	System	09 Sep 2020 20:22:24

US3552371

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered '2018'	System	09 Sep 2020 20:22:24

US3552371

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 20:22:24

US3552371

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 20:22:24

US3552371

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:39:31

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Acute and chronic thyroiditis, PT: Autoimmune thyroiditis, LLT: Hashimoto's disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 20:28:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 20:28:44
Data point term sent to Coder	System	09 Sep 2020 20:24:11
User entered 'hypothyroid/hashimotos'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:23:20

US3552371

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered 'un May 1995'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:23:20

US3552371

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:23:20

US3552371

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:39:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:23:20

US3552371

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:23:20

US3552371

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:39:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:23:20

US3552371

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered 'May 1995'	System	09 Sep 2020 20:23:20

US3552371

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered '1995'	System	09 Sep 2020 20:23:20

US3552371

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 20:23:20

US3552371

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 20:23:20

US3552371

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:39:31

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:50:29
User closed query 'Per DM CLR: Please specify the type and/or location of MUSCLE SORENESS. 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)	27 Oct 2020 09:41:52
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle soreness - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 15:59:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 15:59:41
Data point term sent to Coder	System	26 Oct 2020 15:30:15
Query 'Per DM CLR: Please specify the type and/or location of MUSCLE SORENESS. 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 'Resolved' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 15:29:34
DataPoint Un-verified.	(b) (4), (b) (6)	26 Oct 2020 15:29:25
Coding entries removed.	(b) (4), (b) (6)	26 Oct 2020 15:29:25
User entered 'Generalized MUSCLE SORENESS' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 15:29:25
User opened query 'Per DM CLR: Please specify the type and/or location of MUSCLE SORENESS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 14:48:33
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle soreness - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 20:24:47

US3552371

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:39:31

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	09 Sep 2020 20:24:47
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	09 Sep 2020 20:24:11
User entered 'muscle soreness'	Stanley Dublin (b) (4)	09 Sep 2020 20:23:39
	(b) (4)	

US3552371

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered 'un UNK 2012'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:23:39

US3552371

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:23:39

US3552371

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:39:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:23:39

US3552371

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:23:39

US3552371

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:39:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:23:39

US3552371

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	09 Sep 2020 20:23:39

US3552371

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered '2012'	System	09 Sep 2020 20:23:39

US3552371

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 20:23:39

US3552371

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 20:23:39

US3552371

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:39:31

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 10:12:18
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'done' (Site from DM).	Joan Siegner (b) (4)	06 Oct 2020 13:54:32
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 06:26:05
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac valve therapeutic procedures, PT: Mitral valve repair, LLT: Mitral valve repair - version MedDRA\23.0.	Coder Import (b) (4)	09 Sep 2020 20:24:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	09 Sep 2020 20:24:46
Data point term sent to Coder	System	09 Sep 2020 20:24:11
User entered 'mitral valve repair'	Stanley Doublin (b) (4)	09 Sep 2020 20:24:03

US3552371

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered 'un Apr 1995'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:24:03

US3552371

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:24:03

US3552371

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:39:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:24:03

US3552371

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered 'un Apr 1995'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:24:03

US3552371

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:39:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:24:03

US3552371

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered 'Apr 1995'	System	09 Sep 2020 20:24:03

US3552371

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered '1995'	System	09 Sep 2020 20:24:03

US3552371

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered 'Apr 1995'	System	09 Sep 2020 20:24:03

US3552371

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered '1995'	System	09 Sep 2020 20:24:03

US3552371

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:39:31

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 20:28:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 20:28:54
Data point term sent to Coder	System	09 Sep 2020 20:28:20
User entered 'menopause'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:27:23

US3552371

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered 'un UNK 2018'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:27:23

US3552371

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:27:23

US3552371

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:39:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	09 Sep 2020 20:27:23

US3552371

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:27:23

US3552371

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:39:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:27:23

US3552371

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	09 Sep 2020 20:27:23

US3552371

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered '2018'	System	09 Sep 2020 20:27:23

US3552371

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 20:27:23

US3552371

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 20:27:23

US3552371

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:39:31

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 20:28:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 20:28:54
Data point term sent to Coder	System	09 Sep 2020 20:28:24
User entered 'seasonal allergies'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:28:00

US3552371

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered 'un UNK 2012'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:28:00

US3552371

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:28:00

US3552371

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:39:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:28:00

US3552371

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:28:00

US3552371

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:39:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:28:00

US3552371

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	09 Sep 2020 20:28:00

US3552371

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered '2012'	System	09 Sep 2020 20:28:00

US3552371

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 20:28:00

US3552371

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 20:28:00

US3552371

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:39:31

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 12:39:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 12:39:35
Data point term sent to Coder	System	11 Sep 2020 12:38:46
User closed query 'For coding purposes, please clarify/provide more information for term ALLERGIES. (Seasonal, Food, Dust, etc) One allergy per line' (Site from System).	System	11 Sep 2020 12:37:57
Query 'For coding purposes, please clarify/provide more information for term ALLERGIES. (Seasonal, Food, Dust, etc) One allergy per line' answered with 'done' (Site from System).	Joan Siegner (b) (4)	11 Sep 2020 12:37:57
User entered 'sulfa allergy' reason for change: Data Entry Error	Joan Siegner (b) (4)	11 Sep 2020 12:37:52
User opened query 'For coding purposes, please clarify/provide more information for term ALLERGIES. (Seasonal, Food, Dust, etc) One allergy per line' (Site from System).	Coder Import (b) (4) (b) (4)	10 Sep 2020 13:34:38
Data point term sent to Coder	System	09 Sep 2020 20:28:23
User entered 'allergies'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:28:12

US3552371

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered 'un UNK 2001'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:28:12

US3552371

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:28:12

US3552371

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:39:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:28:12

US3552371

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:28:12

US3552371

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:39:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:28:12

US3552371

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered 'Jan 2001'	System	09 Sep 2020 20:28:12

US3552371

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered '2001'	System	09 Sep 2020 20:28:12

US3552371

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 20:28:12

US3552371

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 20:28:12

US3552371

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:39:31

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac valve disorders, HLT: Mitral valvular disorders, PT: Mitral valve incompetence, LLT: Mitral regurgitation - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 14:13:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 14:13:27
Data point term sent to Coder	System	06 Oct 2020 13:55:49
User entered 'mitral regurgitation'	Joan Siegner (b) (4)	06 Oct 2020 13:55:05

US3552371

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered 'un UNK 1995'	Joan Siegner (b) (4)	06 Oct 2020 13:55:05

US3552371

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered '0'	Joan Siegner (b) (4)	06 Oct 2020 13:55:05

US3552371

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:39:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered 'No (N)'	Joan Siegner (b) (4)	06 Oct 2020 13:55:05

US3552371

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered 'un Apr 1995'	Joan Siegner (b) (4)	06 Oct 2020 13:55:05

US3552371

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:39:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered '0'	Joan Siegner (b) (4)	06 Oct 2020 13:55:05

US3552371

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	06 Oct 2020 13:55:05

US3552371

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered '1995'	System	06 Oct 2020 13:55:05

US3552371

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered 'Apr 1995'	System	06 Oct 2020 13:55:05

US3552371

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered '1995'	System	06 Oct 2020 13:55:05

US3552371

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:53
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:28:44

US3552371

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:47:35
DataPoint Un-verified.	Mikayla Frye (b) (4)	10 Nov 2020 17:35:26
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Mikayla Frye (b) (4)	10 Nov 2020 17:35:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:32:53
User entered '8 Sep 2020'	Stanley Doublin (b) (4)	09 Sep 2020 20:28:44
	(b) (4)	

US3552371

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:53
User entered '16:34'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:28:44

US3552371

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered '08 Sep 2020 16:34'	System	10 Nov 2020 17:35:26
User entered '8 Sep 2020 16:34'	System	09 Sep 2020 20:28:44

US3552371

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:53
User entered '66' in	Stanley Doublin (b) (4)	09 Sep 2020 20:28:44
DataPoint set to visible.	(b) (4) System	08 Sep 2020 21:57:28

US3552371

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:53
User entered '132' lb	Stanley Doublin (b) (4)	09 Sep 2020 20:28:44
DataPoint set to visible.	(b) (4) System	08 Sep 2020 21:57:28

US3552371

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered '21.34990'	System	09 Sep 2020 20:28:44
DataPoint set to visible.	System	08 Sep 2020 21:57:28

US3552371

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	09 Sep 2020 20:28:44
DataPoint set to visible.	System	08 Sep 2020 21:57:28

US3552371

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:53
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:28:44

US3552371

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:53
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:28:44

US3552371

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:53
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:28:44

US3552371

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:53
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:28:44

US3552371

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Sep 2020 20:28:44

US3552371

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:53
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:28:44

US3552371

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Sep 2020 20:28:44

US3552371

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:53
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:28:44

US3552371

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Sep 2020 20:28:44

US3552371

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:53
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:28:44

US3552371

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Sep 2020 20:28:44

US3552371

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:39:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:33:59
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:28:53

US3552371

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:47:43
DataPoint Un-verified.	Mikayla Frye (b) (4)	10 Nov 2020 17:35:30
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Mikayla Frye (b) (4)	10 Nov 2020 17:35:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:33:59
User entered '8 Sep 2020'	Stanley Dublin (b) (4)	09 Sep 2020 20:28:53
	(b) (4)	

US3552371

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:47:48
DataPoint Un-verified.	Mikayla Frye (b) (4)	10 Nov 2020 17:35:36
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Mikayla Frye (b) (4)	10 Nov 2020 17:35:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:34:06
User entered '8 Sep 2020'	Stanley Doublin (b) (4)	09 Sep 2020 20:29:14
	(b) (4)	

US3552371

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:06
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:29:14

US3552371

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:39:31

[If No, what is the reason?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:06
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:29:14

US3552371

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:06
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:29:14

US3552371

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:06
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:29:14

US3552371

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:39:31

[Date of surgery unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:06
User entered '0'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:29:14

US3552371

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:06
User entered 'un Oct 2018'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:29:14

US3552371

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:39:31

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:06
User entered '0'	Stanley Dublin (b) (4) (b) (4)	09 Sep 2020 20:29:14

US3552371

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:20
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:31:34

US3552371

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:20
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:31:34

US3552371

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:20
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:31:34

US3552371

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:20
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:31:34

US3552371

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:20
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:31:34

US3552371

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:20
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:31:34

US3552371

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:20
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	09 Sep 2020 20:31:34

US3552371

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:20
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:31:34

US3552371

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:20
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:31:34

US3552371

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:20
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:31:34

US3552371

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:20
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:31:34

US3552371

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:39:31

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:20
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:31:34

US3552371

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:39:31

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:20
User entered 'in home repairs, visits from daughter and grandchild, travel by plane for work, plays tennis, goes to gym, husband works outside of home, socializing, grocery shopping, restaurant dinning'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:31:34

US3552371

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:39:31

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	09 Sep 2020 20:31:34

US3552371

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:39:31

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:20
User entered '0'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:31:34

US3552371

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:20
User entered '0'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:31:34

US3552371

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:20
User entered '0'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:31:34

US3552371

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:20
User entered '1'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:31:34

US3552371

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:20
User entered '0'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:31:34

US3552371

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:39:31

Other

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	09 Sep 2020 20:31:34

US3552371

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:39:31

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:20
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:31:34

US3552371

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:39:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:29
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:31:53

US3552371

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:47:59
DataPoint Un-verified.	Mikayla Frye (b) (4)	10 Nov 2020 17:35:44
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Mikayla Frye (b) (4)	10 Nov 2020 17:35:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:34:29
User entered '8 Sep 2020'	Stanley Dublin (b) (4)	09 Sep 2020 20:31:53
	(b) (4)	

US3552371

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:29
User entered 'Clinic (Clinic)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:31:53

US3552371

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:39:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	09 Sep 2020 20:31:53

US3552371

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:38
User entered '08 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 21:59:15

US3552371

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:39:31

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:38
User entered '112401'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 21:59:15

US3552371

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:38
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 21:59:15

US3552371

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:38
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:32:03

US3552371

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:38
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	09 Sep 2020 20:32:03

US3552371

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:38
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:32:03

US3552371

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:39:31

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:38
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:32:03

US3552371

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:39:31

[Liver Disease](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:38
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:32:03

US3552371

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:38
User entered 'No (N)'	Stanley Doublin (b) (4)	21 Sep 2020 18:02:44
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 05:44:23
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:44:22

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:39:31

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:36
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:32:46

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:39:31

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:36
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:32:46

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:39:31

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:36
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:32:46

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:39:31

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:36
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:32:46

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:39:31

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Dublin (b) (4)	09 Sep 2020 20:32:46

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:39:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:36
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:32:46

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:39:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:48:11
DataPoint Un-verified.	Mikayla Frye (b) (4)	10 Nov 2020 17:35:53
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 17:35:53
DataPoint Verified.	Mikayla Frye (b) (4)	10 Nov 2020 17:35:53
	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:35:36
	(b) (4)	
User entered '8 Sep 2020'	Stanley Dublin (b) (4)	09 Sep 2020 20:32:46
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:36
User entered '16:34'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:32:46

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered '08 Sep 2020 16:34'	System	10 Nov 2020 17:35:53
User entered '8 Sep 2020 16:34'	System	09 Sep 2020 20:32:46

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:39:31

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:36
User entered '98.7' F	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:32:46

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:39:31

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:36
User entered 'Oral (Oral)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:32:46

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:39:31

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:36
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:32:46

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:39:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:36
User entered '90'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:32:46

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:39:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Sep 2020 20:32:46

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:36
User entered '14'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:32:46

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:39:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Sep 2020 20:32:46

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:39:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:36
User entered '117'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:32:46

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:39:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Sep 2020 20:32:46

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:36
User entered '81'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:32:46

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:39:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Sep 2020 20:32:46

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:39:31

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:36
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:32:46

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:39:31

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:36
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:32:46

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:39:31

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Dublin (b) (4) (b) (4)	09 Sep 2020 20:33:30

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:39:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:36
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:33:30

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:39:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:48:16
DataPoint Un-verified.	Mikayla Frye (b) (4)	10 Nov 2020 17:35:53
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 17:35:53
DataPoint Verified.	Mikayla Frye (b) (4)	10 Nov 2020 17:35:53
	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:35:36
	(b) (4)	
User entered '8 Sep 2020'	Stanley Dublin (b) (4)	09 Sep 2020 20:33:30
	(b) (4)	

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:36
User entered '17:55'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:33:30

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered '08 Sep 2020 17:55'	System	10 Nov 2020 17:35:53
User entered '8 Sep 2020 17:55'	System	09 Sep 2020 20:33:30

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:39:31

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:36
User entered '98.9' F	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:33:30

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:39:31

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:36
User entered 'Oral (Oral)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:33:30

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:39:31

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:36
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:33:30

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:39:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:36
User entered '89'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:33:30

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:39:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Sep 2020 20:33:30

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:36
User entered '14'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:33:30

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:39:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Sep 2020 20:33:30

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:36
User entered '114'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:33:30

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:39:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Sep 2020 20:33:30

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:36
User entered '79'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:33:30

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:39:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Sep 2020 20:33:30

US3552371

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:39:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:46
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:34:41

US3552371

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:39:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:48:25
DataPoint Un-verified.	Mikayla Frye (b) (4)	10 Nov 2020 17:35:58
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 17:35:58
DataPoint Verified.	Mikayla Frye (b) (4)	10 Nov 2020 17:35:58
	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:35:46
User entered '8 Sep 2020'	(b) (4), (b) (6)	
	Stanley Dublin (b) (4)	09 Sep 2020 20:34:41
	(b) (4)	

US3552371

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:39:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:57
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	08 Sep 2020 22:36:24

US3552371

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:39:31

[If No, reason not given](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:57
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	08 Sep 2020 22:36:24

US3552371

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:57
User entered empty.	Cassandra Zehenny (b) (4)	08 Sep 2020 22:36:24
	(b) (4)	

US3552371

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:39:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 22:36:24

US3552371

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:48:31
DataPoint Un-verified.	Mikayla Frye (b) (4)	10 Nov 2020 17:36:04
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 17:36:04
DataPoint Verified.	Mikayla Frye (b) (4)	10 Nov 2020 17:36:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:57
	(b) (4)	
User entered '8 Sep 2020'	Cassandra Zehenny (b) (4)	08 Sep 2020 22:36:24
	(b) (4)	

US3552371

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:57
User entered '17:25'	Cassandra Zehenny (b) (4) (b) (4)	08 Sep 2020 22:36:24

US3552371

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered '08 Sep 2020 17:25'	System	10 Nov 2020 17:36:04
User entered '8 Sep 2020 17:25'	System	08 Sep 2020 22:36:24

US3552371

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:57
User entered 'Left Arm (LEFT ARM)'	Cassandra Zehenny (b) (4)	08 Sep 2020 22:36:24
	(b) (4)	

US3552371

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:57
User entered 'ONCE'	System	08 Sep 2020 22:36:24

US3552371

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 22:36:24

US3552371

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:39:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:36:06
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:34:55

US3552371

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:39:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:48:38
DataPoint Un-verified.	Mikayla Frye (b) (4)	10 Nov 2020 17:36:09
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 17:36:09
DataPoint Verified.	Mikayla Frye (b) (4)	10 Nov 2020 17:36:09
	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:36:06
	(b) (4)	
User entered '8 Sep 2020'	Stanley Dublin (b) (4)	09 Sep 2020 20:34:55
	(b) (4)	

US3552371

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:36:06
User entered '16:52'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:34:55

US3552371

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered '08 Sep 2020 16:52'	System	10 Nov 2020 17:36:09
User entered '8 Sep 2020 16:52'	System	09 Sep 2020 20:34:55

US3552371

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:39:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:48:46
DataPoint Un-verified.	Mikayla Frye (b) (4)	10 Nov 2020 17:36:14
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 17:36:14
DataPoint Verified.	Mikayla Frye (b) (4)	10 Nov 2020 17:36:14
	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:36:14
	(b) (4)	
User entered '8 Sep 2020'	Stanley Dublin (b) (4)	09 Sep 2020 20:35:07
	(b) (4)	

US3552371

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:39:31

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Dublin (b) (4)	09 Sep 2020 20:35:07

US3552371

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:39:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:36:14
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:35:07

US3552371

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:36:14
User entered '16:55'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:35:07

US3552371

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered '08 Sep 2020 16:55'	System	10 Nov 2020 17:36:14
User entered '8 Sep 2020 16:55'	System	09 Sep 2020 20:35:07

US3552371

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:39:31

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Dublin (b) (4)	09 Sep 2020 20:35:07

US3552371

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:39:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:36:14
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:35:07

US3552371

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:36:14
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:35:07

US3552371

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 20:35:07

US3552371

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:36:21
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	16 Sep 2020 14:26:00

US3552371

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:39:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 14:26:00

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 22:36:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:39:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-08T17:51:27', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '858864d4-4162-42b8-b11f-29b80906302c'	System	08 Sep 2020 22:51:49
User entered 'Yes (Y)'	System	08 Sep 2020 22:51:49

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:39:31

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-08T17:51:34', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '858864d4-4162-42b8-b11f-29b80906302c'	System	08 Sep 2020 22:51:49
User entered '98.9'	System	08 Sep 2020 22:51:49

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-08T17:51:38', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '858864d4-4162-42b8-b11f-29b80906302c'	System	08 Sep 2020 22:51:49
User entered 'No (N)'	System	08 Sep 2020 22:51:49

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-08T17:51:45', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '858864d4-4162-42b8-b11f-29b80906302c'	System	08 Sep 2020 22:51:49
User entered '08 Sep 2020 17:51'	System	08 Sep 2020 22:51:49

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 17:45'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 20:15'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 22:36:24
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:39:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-09T09:22:09', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '1f247cf3-2e4f-4dfb-bb25-b61bd9036c85'	System	09 Sep 2020 14:22:33
User entered 'Yes (Y)'	System	09 Sep 2020 14:22:33

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:39:31

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-09T09:22:15', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '1f247cf3-2e4f-4dfb-bb25-b61bd9036c85'	System	09 Sep 2020 14:22:33
User entered '97.1'	System	09 Sep 2020 14:22:33

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-09T09:22:19', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '1f247cf3-2e4f-4dfb-bb25-b61bd9036c85'	System	09 Sep 2020 14:22:33
User entered 'No (N)'	System	09 Sep 2020 14:22:33

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-09T09:22:29', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '1f247cf3-2e4f-4dfb-bb25-b61bd9036c85'	System	09 Sep 2020 14:22:33
User entered '09 Sep 2020 09:22'	System	09 Sep 2020 14:22:33

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 21:10'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 22:36:24
User entered 'Day 2'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:39:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-09T18:22:39', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'feecc07b-12a9-42a5-9c37-3e3a14cbb01e'	System	09 Sep 2020 23:23:12
User entered 'Yes (Y)'	System	09 Sep 2020 23:23:12

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:39:31

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-09T18:22:59', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'feecc07b-12a9-42a5-9c37-3e3a14cbb01e' User entered '98.8'	System	09 Sep 2020 23:23:12

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-09T18:23:05', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'feecc07b-12a9-42a5-9c37-3e3a14cbb01e'	System	09 Sep 2020 23:23:12
User entered 'No (N)'	System	09 Sep 2020 23:23:12

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-09T18:23:10', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'feecc07b-12a9-42a5-9c37-3e3a14cbb01e'	System	09 Sep 2020 23:23:12
User entered '09 Sep 2020 18:23'	System	09 Sep 2020 23:23:12

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 22:36:24
User entered 'Day 3'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:39:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-10T13:19:24', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '49037558-7876-424a-bdea-c6a74910fedf'	System	10 Sep 2020 18:19:43
User entered 'Yes (Y)'	System	10 Sep 2020 18:19:43

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:39:31

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-10T13:19:29', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '49037558-7876-424a-bdea-c6a74910fedf'	System	10 Sep 2020 18:19:43
User entered '98.8'	System	10 Sep 2020 18:19:43

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:39:31

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-10T13:19:33', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '49037558-7876-424a-bdea-c6a74910fedf'	System	10 Sep 2020 18:19:43
User entered 'No (N)'	System	10 Sep 2020 18:19:43

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-10T13:19:41', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '49037558-7876-424a-bdea-c6a74910fedf' User entered '10 Sep 2020 13:19'	System	10 Sep 2020 18:19:43
	System	10 Sep 2020 18:19:43

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 22:36:24
User entered 'Day 4'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:39:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-11T16:45:09', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'd2d0e360-9efc-47fc-b9e6-97a25b4e6714'	System	11 Sep 2020 20:45:24
User entered 'Yes (Y)'	System	11 Sep 2020 20:45:24

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:39:31

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-11T16:45:14', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'd2d0e360-9efc-47fc-b9e6-97a25b4e6714'	System	11 Sep 2020 20:45:24
User entered '98.6'	System	11 Sep 2020 20:45:24

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-11T16:45:17', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'd2d0e360-9efc-47fc-b9e6-97a25b4e6714'	System	11 Sep 2020 20:45:24
User entered 'No (N)'	System	11 Sep 2020 20:45:24

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-11T16:45:22', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'd2d0e360-9efc-47fc-b9e6-97a25b4e6714'	System	11 Sep 2020 20:45:24
User entered '11 Sep 2020 16:45'	System	11 Sep 2020 20:45:24

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 22:36:24
User entered 'Day 5'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:39:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-12T15:25:38', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '45d7e9a0-eb52-4590-a30d-ae5563ba69b3'	System	12 Sep 2020 19:25:53
User entered 'Yes (Y)'	System	12 Sep 2020 19:25:53

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:39:31

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-12T15:25:43', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '45d7e9a0-eb52-4590-a30d-ae5563ba69b3'	System	12 Sep 2020 19:25:53
User entered '98.3'	System	12 Sep 2020 19:25:53

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-12T15:25:46', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '45d7e9a0-eb52-4590-a30d-ae5563ba69b3'	System	12 Sep 2020 19:25:53
User entered 'No (N)'	System	12 Sep 2020 19:25:53

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-12T15:25:51', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '45d7e9a0-eb52-4590-a30d-ae5563ba69b3'	System	12 Sep 2020 19:25:53
User entered '12 Sep 2020 15:25'	System	12 Sep 2020 19:25:53

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 22:36:24
User entered 'Day 6'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:39:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-13T14:28:04', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '26de8d4c-9623-414a-afc4-08ddc213690b'	System	13 Sep 2020 18:29:11
User entered 'Yes (Y)'	System	13 Sep 2020 18:29:11

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:39:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-13T14:28:10', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '26de8d4c-9623-414a-afc4-08ddc213690b' User entered '97.3'	System	13 Sep 2020 18:29:11

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-13T14:28:17', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '26de8d4c-9623-414a-afc4-08ddc213690b'	System	13 Sep 2020 18:29:11
User entered 'No (N)'	System	13 Sep 2020 18:29:11

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-13T14:28:26', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '26de8d4c-9623-414a-afc4-08ddc213690b'	System	13 Sep 2020 18:29:11
User entered '13 Sep 2020 14:28'	System	13 Sep 2020 18:29:11

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 22:36:24
User entered 'Day 7'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:39:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-14T21:33:23', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '9eac374d-d32a-44fa-9aec-34c04f0237c9'	System	15 Sep 2020 02:33:41
User entered 'Yes (Y)'	System	15 Sep 2020 02:33:41

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:39:31

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-14T21:33:30', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '9eac374d-d32a-44fa-9aec-34c04f0237c9'	System	15 Sep 2020 02:33:41
User entered '98.1'	System	15 Sep 2020 02:33:41

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-14T21:33:33', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '9eac374d-d32a-44fa-9aec-34c04f0237c9'	System	15 Sep 2020 02:33:41
User entered 'No (N)'	System	15 Sep 2020 02:33:41

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-14T21:33:36', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '9eac374d-d32a-44fa-9aec-34c04f0237c9'	System	15 Sep 2020 02:33:41
User entered '14 Sep 2020 21:33'	System	15 Sep 2020 02:33:41

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 22:36:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:39:31

[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 (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-08T17:52:12', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '21bd1284-892e-4597-8813-7caf1935b196'	System	08 Sep 2020 22:52:35
User entered 'None (1)'	System	08 Sep 2020 22:52:35

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-08T17:52:15', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '21bd1284-892e-4597-8813-7caf1935b196'	System	08 Sep 2020 22:52:35
User entered 'No (N)'	System	08 Sep 2020 22:52:35

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-08T17:52:19', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '21bd1284-892e-4597-8813-7caf1935b196'	System	08 Sep 2020 22:52:35
User entered 'No (N)'	System	08 Sep 2020 22:52:35

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:39:31

[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 (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-08T17:52:25', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '21bd1284-892e-4597-8813-7caf1935b196'	System	08 Sep 2020 22:52:35
User entered 'None (1)'	System	08 Sep 2020 22:52:35

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-08T17:52:32', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '21bd1284-892e-4597-8813-7caf1935b196'	System	08 Sep 2020 22:52:35
User entered '08 Sep 2020 17:52'	System	08 Sep 2020 22:52:35

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 17:45'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 20:15'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 22:36:24
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:39:31

[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 (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-09T09:22:43', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '402a3b06-4232-45ea-9e59-46f3c6bdd9ba'	System	09 Sep 2020 14:23:13
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 14:23:13

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-09T09:22:47', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '402a3b06-4232-45ea-9e59-46f3c6bdd9ba'	System	09 Sep 2020 14:23:13
User entered 'No (N)'	System	09 Sep 2020 14:23:13

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-09T09:22:56', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '402a3b06-4232-45ea-9e59-46f3c6bdd9ba' User entered 'No (N)'	System	09 Sep 2020 14:23:13

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:39:31

[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 (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-09T09:23:03', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '402a3b06-4232-45ea-9e59-46f3c6bdd9ba'	System	09 Sep 2020 14:23:13
User entered 'None (1)'	System	09 Sep 2020 14:23:13

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-09T09:23:10', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '402a3b06-4232-45ea-9e59-46f3c6bdd9ba' User entered '09 Sep 2020 09:23'	System	09 Sep 2020 14:23:13
	System	09 Sep 2020 14:23:13

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 21:10'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 22:36:24
User entered 'Day 2'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:39:31

[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 (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-09T18:23:23', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '6fe7adfd-120b-4fe9-968d-6a190bdc5472'	System	09 Sep 2020 23:24:05
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 23:24:05

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-09T18:23:38', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '6fe7adfd-120b-4fe9-968d-6a190bdc5472'	System	09 Sep 2020 23:24:05
User entered 'No (N)'	System	09 Sep 2020 23:24:05

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-09T18:23:51', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '6fe7adfd-120b-4fe9-968d-6a190bdc5472'	System	09 Sep 2020 23:24:05
User entered 'No (N)'	System	09 Sep 2020 23:24:05

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:39:31

[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 (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-09T18:23:58', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '6fe7adfd-120b-4fe9-968d-6a190bdc5472'	System	09 Sep 2020 23:24:05
User entered 'None (1)'	System	09 Sep 2020 23:24:05

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-09T18:24:02', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '6fe7adfd-120b-4fe9-968d-6a190bdc5472'	System	09 Sep 2020 23:24:05
User entered '09 Sep 2020 18:24'	System	09 Sep 2020 23:24:05

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 22:36:24
User entered 'Day 3'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:39:31

[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 (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-10T13:19:50', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '91206431-88de-4a29-af34-aeb1ab2d4ea1'	System	10 Sep 2020 18:20:17
User entered 'None (1)'	System	10 Sep 2020 18:20:17

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-10T13:19:53', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '91206431-88de-4a29-af34-aeb1ab2d4ea1'	System	10 Sep 2020 18:20:17
User entered 'No (N)'	System	10 Sep 2020 18:20:17

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-10T13:19:56', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '91206431-88de-4a29-af34-aeb1ab2d4ea1'	System	10 Sep 2020 18:20:17
User entered 'No (N)'	System	10 Sep 2020 18:20:17

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:39:31

[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 (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-10T13:20:10', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '91206431-88de-4a29-af34-aeb1ab2d4ea1'	System	10 Sep 2020 18:20:17
User entered 'None (1)'	System	10 Sep 2020 18:20:17

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-10T13:20:14', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '91206431-88de-4a29-af34-aeb1ab2d4ea1'	System	10 Sep 2020 18:20:17
User entered '10 Sep 2020 13:20'	System	10 Sep 2020 18:20:17

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 22:36:24
User entered 'Day 4'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:39:31

[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 (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-11T16:44:41', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '15c5f96f-366d-4c61-9922-2faca3635568'	System	11 Sep 2020 20:44:59
User entered 'None (1)'	System	11 Sep 2020 20:44:59

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:39:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-11T16:44:49', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '15c5f96f-366d-4c61-9922-2faca3635568'	System	11 Sep 2020 20:44:59
User entered 'No (N)'	System	11 Sep 2020 20:44:59

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-11T16:44:51', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '15c5f96f-366d-4c61-9922-2faca3635568'	System	11 Sep 2020 20:44:59
User entered 'No (N)'	System	11 Sep 2020 20:44:59

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:39:31

[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 (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-11T16:44:55', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '15c5f96f-366d-4c61-9922-2faca3635568'	System	11 Sep 2020 20:44:59
User entered 'None (1)'	System	11 Sep 2020 20:44:59

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-11T16:44:57', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '15c5f96f-366d-4c61-9922-2faca3635568'	System	11 Sep 2020 20:44:59
User entered '11 Sep 2020 16:44'	System	11 Sep 2020 20:44:59

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 22:36:24
User entered 'Day 5'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:39:31

[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 (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-12T15:25:13', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'a6dd3187-b43b-4f7b-af01-7938548175da'	System	12 Sep 2020 19:25:28
User entered 'None (1)'	System	12 Sep 2020 19:25:28

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-12T15:25:16', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'a6dd3187-b43b-4f7b-af01-7938548175da'	System	12 Sep 2020 19:25:28
User entered 'No (N)'	System	12 Sep 2020 19:25:28

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-12T15:25:18', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'a6dd3187-b43b-4f7b-af01-7938548175da'	System	12 Sep 2020 19:25:28
User entered 'No (N)'	System	12 Sep 2020 19:25:28

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:39:31

[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 (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-12T15:25:20', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'a6dd3187-b43b-4f7b-af01-7938548175da'	System	12 Sep 2020 19:25:28
User entered 'None (1)'	System	12 Sep 2020 19:25:28

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-12T15:25:23', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'a6dd3187-b43b-4f7b-af01-7938548175da'	System	12 Sep 2020 19:25:28
User entered '12 Sep 2020 15:25'	System	12 Sep 2020 19:25:28

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 22:36:24
User entered 'Day 6'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:39:31

[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 (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-13T14:28:29', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '7b1f7bb8-fa45-48b0-a11b-104a9ede69b6'	System	13 Sep 2020 18:29:14
User entered 'None (1)'	System	13 Sep 2020 18:29:14

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-13T14:28:32', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '7b1f7bb8-fa45-48b0-a11b-104a9ede69b6'	System	13 Sep 2020 18:29:14
User entered 'No (N)'	System	13 Sep 2020 18:29:14

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-13T14:28:34', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '7b1f7bb8-fa45-48b0-a11b-104a9ede69b6'	System	13 Sep 2020 18:29:14
User entered 'No (N)'	System	13 Sep 2020 18:29:14

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:39:31

[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 (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-13T14:28:37', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '7b1f7bb8-fa45-48b0-a11b-104a9ede69b6'	System	13 Sep 2020 18:29:14
User entered 'None (1)'	System	13 Sep 2020 18:29:14

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-13T14:28:40', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '7b1f7bb8-fa45-48b0-a11b-104a9ede69b6'	System	13 Sep 2020 18:29:14
User entered '13 Sep 2020 14:28'	System	13 Sep 2020 18:29:14

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 22:36:24
User entered 'Day 7'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:39:31

[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 (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-14T21:33:40', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'ad599caf-1856-4ea3-bdc2-1a2a089baff6'	System	15 Sep 2020 02:33:53
User entered 'None (1)'	System	15 Sep 2020 02:33:53

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-14T21:33:43', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'ad599caf-1856-4ea3-bdc2-1a2a089baff6'	System	15 Sep 2020 02:33:53
User entered 'No (N)'	System	15 Sep 2020 02:33:53

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-14T21:33:45', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'ad599caf-1856-4ea3-bdc2-1a2a089baff6'	System	15 Sep 2020 02:33:53
User entered 'No (N)'	System	15 Sep 2020 02:33:53

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:39:31

[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 (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-14T21:33:48', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'ad599caf-1856-4ea3-bdc2-1a2a089baff6'	System	15 Sep 2020 02:33:53
User entered 'None (1)'	System	15 Sep 2020 02:33:53

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-14T21:33:51', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'ad599caf-1856-4ea3-bdc2-1a2a089baff6'	System	15 Sep 2020 02:33:53
User entered '14 Sep 2020 21:33'	System	15 Sep 2020 02:33:53

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 22:36:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:39:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-08T17:52:40', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '5f69611a-e0c1-438e-98c0-b4240dff81ab'	System	08 Sep 2020 22:53:17
User entered 'None (0)'	System	08 Sep 2020 22:53:17

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:39:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-08T17:52:46', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '5f69611a-e0c1-438e-98c0-b4240dff81ab'	System	08 Sep 2020 22:53:17
User entered 'None (0)'	System	08 Sep 2020 22:53:17

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:39:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-08T17:52:49', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '5f69611a-e0c1-438e-98c0-b4240dff81ab' User entered 'None (0)'	System	08 Sep 2020 22:53:17

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:39:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-08T17:52:52', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '5f69611a-e0c1-438e-98c0-b4240dff81ab' User entered 'None (0)'	System	08 Sep 2020 22:53:17

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:39:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-08T17:52:57', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '5f69611a-e0c1-438e-98c0-b4240dff81ab'	System	08 Sep 2020 22:53:17
User entered 'None (0)'	System	08 Sep 2020 22:53:17

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:39:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-08T17:53:03', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '5f69611a-e0c1-438e-98c0-b4240dff81ab' User entered 'None (0)'	System	08 Sep 2020 22:53:17

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:39:31

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 (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-08T17:53:11', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '5f69611a-e0c1-438e-98c0-b4240dff81ab'	System	08 Sep 2020 22:53:17
User entered 'No (N)'	System	08 Sep 2020 22:53:17

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:39:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-08T17:53:16', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '5f69611a-e0c1-438e-98c0-b4240dff81ab'	System	08 Sep 2020 22:53:17
User entered '08 Sep 2020 17:53'	System	08 Sep 2020 22:53:17

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 17:45'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 20:15'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 22:36:24
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:39:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-09T09:23:20', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'bc5c4285-00d5-4130-8fe3-90851678f927'	System	09 Sep 2020 14:23:47
User entered 'None (0)'	System	09 Sep 2020 14:23:47

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:39:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-09T09:23:26', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'bc5c4285-00d5-4130-8fe3-90851678f927'	System	09 Sep 2020 14:23:47
User entered 'None (0)'	System	09 Sep 2020 14:23:47

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:39:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-09T09:23:28', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'bc5c4285-00d5-4130-8fe3-90851678f927'	System	09 Sep 2020 14:23:47
User entered 'None (0)'	System	09 Sep 2020 14:23:47

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:39:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-09T09:23:31', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'bc5c4285-00d5-4130-8fe3-90851678f927'	System	09 Sep 2020 14:23:47
User entered 'None (0)'	System	09 Sep 2020 14:23:47

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:39:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-09T09:23:34', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'bc5c4285-00d5-4130-8fe3-90851678f927'	System	09 Sep 2020 14:23:47
User entered 'None (0)'	System	09 Sep 2020 14:23:47

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:39:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-09T09:23:36', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'bc5c4285-00d5-4130-8fe3-90851678f927'	System	09 Sep 2020 14:23:47
User entered 'None (0)'	System	09 Sep 2020 14:23:47

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:39:31

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 (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-09T09:23:40', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'bc5c4285-00d5-4130-8fe3-90851678f927'	System	09 Sep 2020 14:23:47
User entered 'No (N)'	System	09 Sep 2020 14:23:47

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:39:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-09T09:23:44', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'bc5c4285-00d5-4130-8fe3-90851678f927'	System	09 Sep 2020 14:23:47
User entered '09 Sep 2020 09:23'	System	09 Sep 2020 14:23:47

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 21:10'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 22:36:24
User entered 'Day 2'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:39:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-09T18:24:10', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '3390474a-3837-48fd-9373-cbfa71436b21'	System	09 Sep 2020 23:24:41
User entered 'None (0)'	System	09 Sep 2020 23:24:41

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:39:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-09T18:24:16', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '3390474a-3837-48fd-9373-cbfa71436b21'	System	09 Sep 2020 23:24:41
User entered 'None (0)'	System	09 Sep 2020 23:24:41

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:39:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-09T18:24:22', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '3390474a-3837-48fd-9373-cbfa71436b21'	System	09 Sep 2020 23:24:41
User entered 'None (0)'	System	09 Sep 2020 23:24:41

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:39:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-09T18:24:26', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '3390474a-3837-48fd-9373-cbfa71436b21'	System	09 Sep 2020 23:24:41
User entered 'None (0)'	System	09 Sep 2020 23:24:41

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:39:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-09T18:24:30', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '3390474a-3837-48fd-9373-cbfa71436b21'	System	09 Sep 2020 23:24:41
User entered 'None (0)'	System	09 Sep 2020 23:24:41

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:39:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-09T18:24:33', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '3390474a-3837-48fd-9373-cbfa71436b21'	System	09 Sep 2020 23:24:41
User entered 'None (0)'	System	09 Sep 2020 23:24:41

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:39:31

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 (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-09T18:24:36', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '3390474a-3837-48fd-9373-cbfa71436b21'	System	09 Sep 2020 23:24:41
User entered 'No (N)'	System	09 Sep 2020 23:24:41

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:39:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-09T18:24:39', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '3390474a-3837-48fd-9373-cbfa71436b21'	System	09 Sep 2020 23:24:41
User entered '09 Sep 2020 18:24'	System	09 Sep 2020 23:24:41

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 22:36:24
User entered 'Day 3'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:39:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-10T13:20:18', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '125c9178-f320-4566-b039-29f79b0c1d76'	System	10 Sep 2020 18:20:55
User entered 'None (0)'	System	10 Sep 2020 18:20:55

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:39:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-10T13:20:20', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '125c9178-f320-4566-b039-29f79b0c1d76'	System	10 Sep 2020 18:20:55
User entered 'None (0)'	System	10 Sep 2020 18:20:55

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:39:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-10T13:20:23', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '125c9178-f320-4566-b039-29f79b0c1d76'	System	10 Sep 2020 18:20:55
User entered 'None (0)'	System	10 Sep 2020 18:20:55

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:39:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-10T13:20:25', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '125c9178-f320-4566-b039-29f79b0c1d76'	System	10 Sep 2020 18:20:55
User entered 'None (0)'	System	10 Sep 2020 18:20:55

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:39:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-10T13:20:37', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '125c9178-f320-4566-b039-29f79b0c1d76'	System	10 Sep 2020 18:20:55
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	10 Sep 2020 18:20:55

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:39:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-10T13:20:40', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '125c9178-f320-4566-b039-29f79b0c1d76'	System	10 Sep 2020 18:20:55
User entered 'None (0)'	System	10 Sep 2020 18:20:55

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:39:31

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 (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-10T13:20:45', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '125c9178-f320-4566-b039-29f79b0c1d76'	System	10 Sep 2020 18:20:55
User entered 'No (N)'	System	10 Sep 2020 18:20:55

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:39:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-10T13:20:50', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '125c9178-f320-4566-b039-29f79b0c1d76'	System	10 Sep 2020 18:20:55
User entered '10 Sep 2020 13:20'	System	10 Sep 2020 18:20:55

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 22:36:24
User entered 'Day 4'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:39:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-11T16:44:12', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '13dcca6f-5414-4b8c-9bf7-57b213de8833'	System	11 Sep 2020 20:44:40
User entered 'None (0)'	System	11 Sep 2020 20:44:40

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:39:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-11T16:44:20', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '13dcca6f-5414-4b8c-9bf7-57b213de8833'	System	11 Sep 2020 20:44:40
User entered 'No interference with activity (1)'	System	11 Sep 2020 20:44:40

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:39:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-11T16:44:23', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '13dcca6f-5414-4b8c-9bf7-57b213de8833'	System	11 Sep 2020 20:44:40
User entered 'None (0)'	System	11 Sep 2020 20:44:40

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:39:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-11T16:44:26', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '13dcca6f-5414-4b8c-9bf7-57b213de8833'	System	11 Sep 2020 20:44:40
User entered 'None (0)'	System	11 Sep 2020 20:44:40

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:39:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-11T16:44:28', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '13dcca6f-5414-4b8c-9bf7-57b213de8833'	System	11 Sep 2020 20:44:40
User entered 'None (0)'	System	11 Sep 2020 20:44:40

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:39:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-11T16:44:31', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '13dcca6f-5414-4b8c-9bf7-57b213de8833'	System	11 Sep 2020 20:44:40
User entered 'None (0)'	System	11 Sep 2020 20:44:40

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:39:31

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 (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-11T16:44:34', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '13dcca6f-5414-4b8c-9bf7-57b213de8833'	System	11 Sep 2020 20:44:40
User entered 'No (N)'	System	11 Sep 2020 20:44:40

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:39:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-11T16:44:36', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '13dcca6f-5414-4b8c-9bf7-57b213de8833'	System	11 Sep 2020 20:44:40
User entered '11 Sep 2020 16:44'	System	11 Sep 2020 20:44:40

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 22:36:24
User entered 'Day 5'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:39:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-12T15:24:47', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '56aa728f-00e4-4f2e-ae22-b665d7a312db'	System	12 Sep 2020 19:25:11
User entered 'None (0)'	System	12 Sep 2020 19:25:11

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:39:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-12T15:24:50', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '56aa728f-00e4-4f2e-ae22-b665d7a312db'	System	12 Sep 2020 19:25:11
User entered 'None (0)'	System	12 Sep 2020 19:25:11

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:39:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-12T15:24:53', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '56aa728f-00e4-4f2e-ae22-b665d7a312db' User entered 'None (0)'	System	12 Sep 2020 19:25:11

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:39:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-12T15:24:56', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '56aa728f-00e4-4f2e-ae22-b665d7a312db'	System	12 Sep 2020 19:25:11
User entered 'None (0)'	System	12 Sep 2020 19:25:11

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:39:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-12T15:25:02', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '56aa728f-00e4-4f2e-ae22-b665d7a312db'	System	12 Sep 2020 19:25:11
User entered 'None (0)'	System	12 Sep 2020 19:25:11

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:39:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-12T15:25:04', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '56aa728f-00e4-4f2e-ae22-b665d7a312db'	System	12 Sep 2020 19:25:11
User entered 'None (0)'	System	12 Sep 2020 19:25:11

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:39:31

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 (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-12T15:25:06', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '56aa728f-00e4-4f2e-ae22-b665d7a312db'	System	12 Sep 2020 19:25:11
User entered 'No (N)'	System	12 Sep 2020 19:25:11

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:39:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-12T15:25:09', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '56aa728f-00e4-4f2e-ae22-b665d7a312db' User entered '12 Sep 2020 15:25'	System	12 Sep 2020 19:25:11
	System	12 Sep 2020 19:25:11

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 22:36:24
User entered 'Day 6'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:39:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-13T14:28:43', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'aac503af-8924-4377-8721-4c6da971443a'	System	13 Sep 2020 18:29:25
User entered 'None (0)'	System	13 Sep 2020 18:29:25

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:39:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-13T14:28:45', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'aac503af-8924-4377-8721-4c6da971443a'	System	13 Sep 2020 18:29:25
User entered 'None (0)'	System	13 Sep 2020 18:29:25

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:39:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-13T14:28:46', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'aac503af-8924-4377-8721-4c6da971443a'	System	13 Sep 2020 18:29:25
User entered 'None (0)'	System	13 Sep 2020 18:29:25

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:39:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-13T14:29:03', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'aac503af-8924-4377-8721-4c6da971443a'	System	13 Sep 2020 18:29:25
User entered 'None (0)'	System	13 Sep 2020 18:29:25

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:39:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-13T14:29:06', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'aac503af-8924-4377-8721-4c6da971443a'	System	13 Sep 2020 18:29:25
User entered 'None (0)'	System	13 Sep 2020 18:29:25

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:39:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-13T14:29:16', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'aac503af-8924-4377-8721-4c6da971443a'	System	13 Sep 2020 18:29:25
User entered 'None (0)'	System	13 Sep 2020 18:29:25

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:39:31

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 (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-13T14:29:18', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'aac503af-8924-4377-8721-4c6da971443a'	System	13 Sep 2020 18:29:25
User entered 'No (N)'	System	13 Sep 2020 18:29:25

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:39:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-13T14:29:22', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'aac503af-8924-4377-8721-4c6da971443a'	System	13 Sep 2020 18:29:25
User entered '13 Sep 2020 14:29'	System	13 Sep 2020 18:29:25

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 22:36:24
User entered 'Day 7'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:39:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-14T21:33:56', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'c6ce3215-83e1-4b32-97cf-76538ea19033'	System	15 Sep 2020 02:34:23
User entered 'None (0)'	System	15 Sep 2020 02:34:23

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:39:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-14T21:33:59', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'c6ce3215-83e1-4b32-97cf-76538ea19033'	System	15 Sep 2020 02:34:23
User entered 'No interference with activity (1)'	System	15 Sep 2020 02:34:23

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:39:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-14T21:34:02', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'c6ce3215-83e1-4b32-97cf-76538ea19033'	System	15 Sep 2020 02:34:23
User entered 'None (0)'	System	15 Sep 2020 02:34:23

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:39:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-14T21:34:08', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'c6ce3215-83e1-4b32-97cf-76538ea19033'	System	15 Sep 2020 02:34:23
User entered 'No interference with activity (1)'	System	15 Sep 2020 02:34:23

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:39:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-14T21:34:13', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'c6ce3215-83e1-4b32-97cf-76538ea19033'	System	15 Sep 2020 02:34:23
User entered 'None (0)'	System	15 Sep 2020 02:34:23

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:39:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-14T21:34:15', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'c6ce3215-83e1-4b32-97cf-76538ea19033'	System	15 Sep 2020 02:34:23
User entered 'None (0)'	System	15 Sep 2020 02:34:23

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:39:31

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 (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-14T21:34:17', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'c6ce3215-83e1-4b32-97cf-76538ea19033'	System	15 Sep 2020 02:34:23
User entered 'No (N)'	System	15 Sep 2020 02:34:23

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:39:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-14T21:34:21', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'c6ce3215-83e1-4b32-97cf-76538ea19033'	System	15 Sep 2020 02:34:23
User entered '14 Sep 2020 21:34'	System	15 Sep 2020 02:34:23

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 22:36:24

US3552371

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 02:34:23
User entered 'Day 8'	System	15 Sep 2020 02:34:23

US3552371

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-15T16:17:15', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '3dde7c77-93c1-4336-9e3e-2feba0bfe1a9'	System	15 Sep 2020 21:17:26
User entered 'None (0)'	System	15 Sep 2020 21:17:26

US3552371

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-15T16:17:22', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '3dde7c77-93c1-4336-9e3e-2feba0bfe1a9'	System	15 Sep 2020 21:17:26
User entered '15 Sep 2020 16:17'	System	15 Sep 2020 21:17:26

US3552371

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	15 Sep 2020 02:34:23

US3552371

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 02:34:23

US3552371

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 02:34:23
User entered 'Day 8'	System	15 Sep 2020 02:34:23

US3552371

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-15T16:17:26', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '16a1b671-f291-4bd6-b80f-fe96ad1ae316'	System	15 Sep 2020 21:17:33
User entered 'None (0)'	System	15 Sep 2020 21:17:33

US3552371

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:39:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-15T16:17:29', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '16a1b671-f291-4bd6-b80f-fe96ad1ae316'	System	15 Sep 2020 21:17:33
User entered '15 Sep 2020 16:17'	System	15 Sep 2020 21:17:33

US3552371

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	15 Sep 2020 02:34:23

US3552371

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 02:34:23

US3552371

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 02:34:23
User entered 'Day 8'	System	15 Sep 2020 02:34:23

US3552371

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:39:31

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 (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-15T16:17:32', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '53da9a36-1eae-491f-8d67-7a16ef3f81d2'	System	15 Sep 2020 21:17:39
User entered 'No (N)'	System	15 Sep 2020 21:17:39

US3552371

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:39:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-09-15T16:17:35', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '53da9a36-1eae-491f-8d67-7a16ef3f81d2'	System	15 Sep 2020 21:17:39
User entered '15 Sep 2020 16:17'	System	15 Sep 2020 21:17:39

US3552371

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	15 Sep 2020 02:34:23

US3552371

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 02:34:23

US3552371

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:39:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:37:15
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	16 Sep 2020 14:26:10

US3552371

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:39:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:37:15
User entered '15 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	16 Sep 2020 14:26:10

US3552371

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:39:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:37:15
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4) (b) (4)	16 Sep 2020 14:26:10

US3552371

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:39:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:37:15
User entered empty.	Stanley Doublin (b) (4) (b) (4)	16 Sep 2020 14:26:10

US3552371

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:39:53
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 15:08:27

US3552371

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:39:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 15:08:27

US3552371

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:39:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:40:03
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 15:08:36

US3552371

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:39:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:40:03
User entered '22 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 15:08:36

US3552371

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:39:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:40:03
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 15:08:36

US3552371

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:39:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:40:03
User entered empty.	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 15:08:36

US3552371

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:40:08
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:55:11

US3552371

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:39:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 16:55:11

US3552371

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:39:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:41:55
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:55:19

US3552371

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:39:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:41:55
User entered '29 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:55:19

US3552371

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:39:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:41:55
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:55:19

US3552371

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:39:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:41:55
User entered empty.	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:55:19

US3552371

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:42:03
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 16:56:15

US3552371

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:39:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 16:56:15

US3552371

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:39:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:42:12
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 16:56:25

US3552371

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:42:12
User entered '13 Oct 2020'	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 16:56:25

US3552371

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:42:12
User entered 'Clinic (Clinic)'	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 16:56:25

US3552371

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:39:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	13 Oct 2020 16:56:25

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:39:31

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4)	13 Oct 2020 16:57:25

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:39:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:04
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 16:57:25

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:04
User entered '13 Oct 2020'	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 16:57:25

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:04
User entered '10:05'	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 16:57:25

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered '13 Oct 2020 10:05'	System	13 Oct 2020 16:57:25

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:39:31

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:04
User entered '97.9' F	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 16:57:25

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:39:31

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:04
User entered 'Oral (Oral)'	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 16:57:25

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:39:31

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:04
User entered empty.	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 16:57:25

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:39:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:04
User entered '99'	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 16:57:25

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:39:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Oct 2020 16:57:25

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:04
User entered '16'	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 16:57:25

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:39:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Oct 2020 16:57:25

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:04
User entered '137'	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 16:57:25

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:39:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 16:57:25

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:04
User entered '89'	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 16:57:25

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:39:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 16:57:25

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:39:31

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Dublin (b) (4) (b) (4)	13 Oct 2020 16:58:37

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:39:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:04
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 16:58:37

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:04
User entered empty.	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 16:58:37

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:04
User entered empty.	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 16:58:37

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 16:58:37

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:39:31

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:04
User entered empty.	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 16:58:37

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:39:31

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:04
User entered empty.	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 16:58:37

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:39:31

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:04
User entered empty.	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 16:58:37

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:39:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:04
User entered empty.	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 16:58:37

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:39:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 16:58:37

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:04
User entered empty.	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 16:58:37

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:39:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 16:58:37

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:04
User entered empty.	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 16:58:37

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:39:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 16:58:37

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:04
User entered empty.	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 16:58:37

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:39:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 16:58:37

US3552371

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:39:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:33
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 16:58:49

US3552371

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:33
User entered '13 Oct 2020'	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 16:58:49

US3552371

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:39:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:39
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 17:02:53

US3552371

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:39:31

If No, reason not given

Audit	User	Time (GMT)
User closed query 'Please change reason to AE , not PIs decision, and enter AE term Elevated Liver enzymes' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 19:46:24
Query 'Please change reason to AE , not PIs decision, and enter AE term Elevated Liver enzymes' answered with 'physician withheld due to AE of elevated liver enzymes, which is the option currently selected. should it be changed to "other" instead? Thanks' (Site from CRA).	Cassandra Zehenny (b) (4)	28 Oct 2020 21:17:25
User opened query 'Please change reason to AE , not PIs decision, and enter AE term Elevated Liver enzymes' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 20:54:40
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:39
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	Stanley Doublin (b) (4)	13 Oct 2020 17:02:53

US3552371

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:08:38
User closed query 'Please add AE (Elevated liver enzymes) ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 17:08:24
Query 'Please add AE (Elevated liver enzymes) ' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4)	18 Nov 2020 16:02:28
DataPoint Un-verified.	(b) (4)	
	Cassandra Zehenny (b) (4)	18 Nov 2020 16:02:10
	(b) (4)	
User entered 'Elevated liver enzymes' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	18 Nov 2020 16:02:10
	(b) (4)	
User opened query 'Please add AE (Elevated liver enzymes) ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 02:36:46
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:39
User entered empty.	Stanley Doublin (b) (4)	13 Oct 2020 17:02:53
	(b) (4)	

US3552371

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:39:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 17:02:53

US3552371

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:39
User entered empty.	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 17:02:53

US3552371

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:39
User entered empty.	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 17:02:53

US3552371

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 17:02:53

US3552371

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:39
User entered empty.	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 17:02:53

US3552371

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:39
User entered empty.	System	13 Oct 2020 17:02:53

US3552371

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 17:02:53

US3552371

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:39:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:48
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 17:03:46

US3552371

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:48
User entered '13 Oct 2020'	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 17:03:46

US3552371

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:48
User entered '10:53'	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 17:03:46

US3552371

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered '13 Oct 2020 10:53'	System	13 Oct 2020 17:03:46

US3552371

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:55
User entered '13 Oct 2020'	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 17:03:58

US3552371

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:39:31

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Dublin (b) (4)	13 Oct 2020 17:03:58

US3552371

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:39:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:55
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 17:03:58

US3552371

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:55
User entered '10:55'	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 17:03:58

US3552371

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered '13 Oct 2020 10:55'	System	13 Oct 2020 17:03:58

US3552371

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:39:31

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Dublin (b) (4)	13 Oct 2020 17:03:58

US3552371

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:39:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:55
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 17:03:58

US3552371

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:55
User entered empty.	Stanley Doublin (b) (4) (b) (4)	13 Oct 2020 17:03:58

US3552371

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 17:03:58

US3552371

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:55:11
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	20 Oct 2020 17:43:50

US3552371

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:39:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 17:43:50

US3552371

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:39:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:55:20
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	20 Oct 2020 17:43:59

US3552371

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:39:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:55:20
User entered '20 Oct 2020'	Stanley Doublin (b) (4) (b) (4)	20 Oct 2020 17:43:59

US3552371

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:39:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:55:20
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4) (b) (4)	20 Oct 2020 17:43:59

US3552371

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:39:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:55:20
User entered empty.	Stanley Doublin (b) (4) (b) (4)	20 Oct 2020 17:43:59

US3552371

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:55:27
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	27 Oct 2020 15:18:40

US3552371

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:39:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 15:18:40

US3552371

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:39:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:55:36
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	27 Oct 2020 15:18:52

US3552371

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:39:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:55:36
User entered '27 Oct 2020'	Stanley Doublin (b) (4) (b) (4)	27 Oct 2020 15:18:52

US3552371

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:39:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:55:36
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4) (b) (4)	27 Oct 2020 15:18:52

US3552371

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:39:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:55:36
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Oct 2020 15:18:52

US3552371

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:25:24
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	03 Nov 2020 16:16:53

US3552371

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:39:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 16:16:53

US3552371

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:39:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:26:01
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	03 Nov 2020 16:17:03

US3552371

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:39:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 00:51:51
DataPoint Un-verified.	Mikayla Frye (b) (4)	10 Nov 2020 17:36:41
User entered '03 Nov 2020' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 17:36:41
DataPoint Verified.	Mikayla Frye (b) (4)	10 Nov 2020 17:36:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:26:01
	(b) (4)	
User entered '3 Nov 2020'	Stanley Dublin (b) (4)	03 Nov 2020 16:17:03
	(b) (4)	

US3552371

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:39:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:26:01
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4) (b) (4)	03 Nov 2020 16:17:03

US3552371

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:39:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:26:01
User entered empty.	Stanley Doublin (b) (4) (b) (4)	03 Nov 2020 16:17:03

US3552371

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:20:36
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 17:07:02

US3552371

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:39:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 17:07:02

US3552371

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:39:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:20:41
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 17:07:11

US3552371

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:20:41
User entered '10 Nov 2020'	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 17:07:11

US3552371

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:20:41
User entered 'Clinic (Clinic)'	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 17:07:11

US3552371

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:39:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	10 Nov 2020 17:07:11

US3552371

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:20:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 17:07:17

US3552371

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:20:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 17:07:17

US3552371

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:20:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 17:07:17

US3552371

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 17:07:17

US3552371

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:20:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 17:07:17

US3552371

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:20:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 17:07:17

US3552371

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:20:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 17:07:17

US3552371

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:20:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 17:07:17

US3552371

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 17:07:17

US3552371

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:20:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 17:07:17

US3552371

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 17:07:17

US3552371

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:20:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 17:07:17

US3552371

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 17:07:17

US3552371

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:20:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 17:07:17

US3552371

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:39:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 17:07:17

US3552371

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:39:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:20:55
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 17:07:23

US3552371

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:39:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:20:55
User entered empty.	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 17:07:23

US3552371

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:39:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:00
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 17:07:35

US3552371

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:00
User entered '10 Nov 2020'	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 17:07:35

US3552371

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:00
User entered '10:44'	Stanley Doublin (b) (4) (b) (4)	10 Nov 2020 17:07:35

US3552371

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
User entered '10 Nov 2020 10:44'	System	10 Nov 2020 17:07:35

US3552371

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 22:36:24
User entered 'Day 64'	System	08 Sep 2020 22:36:24

US3552371

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[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 (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-11-10T10:38:06', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '2eb066b3-0470-41b6-bbf2-4e8e91219b3d' User entered 'No (N)'	System	10 Nov 2020 16:38:17

US3552371

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

Have you been exposed to someone with 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 (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-11-10T10:38:10', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '2eb066b3-0470-41b6-bbf2-4e8e91219b3d'	System	10 Nov 2020 16:38:17
User entered 'No (N)'	System	10 Nov 2020 16:38:17

US3552371

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-11-10T10:38:13', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '2eb066b3-0470-41b6-bbf2-4e8e91219b3d' User entered '10 Nov 2020 10:38:13'	System	10 Nov 2020 16:38:17
	System	10 Nov 2020 16:38:17

US3552371

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 22:36:24
User entered '08 Nov 2020 00:01'	System	08 Sep 2020 22:36:24

US3552371

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 22:36:24
User entered '12 Nov 2020 23:59'	System	08 Sep 2020 22:36:24

US3552371

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 22:36:24
User entered 'Day 71'	System	08 Sep 2020 22:36:24

US3552371

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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 (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-11-19T11:25:59', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'b0f199fb-63ef-4b35-b8af-5b3a334ac025'	System	19 Nov 2020 17:26:49
User entered 'Yes (Y)'	System	19 Nov 2020 17:26:49

US3552371

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

Have you been exposed to someone with 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 (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-11-19T11:26:04', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'b0f199fb-63ef-4b35-b8af-5b3a334ac025'	System	19 Nov 2020 17:26:49
User entered 'No (N)'	System	19 Nov 2020 17:26:49

US3552371

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[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 (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-11-19T11:26:09', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'b0f199fb-63ef-4b35-b8af-5b3a334ac025'	System	19 Nov 2020 17:26:49
User entered 'No (N)'	System	19 Nov 2020 17:26:49

US3552371

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[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 (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-11-19T11:26:23', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'b0f199fb-63ef-4b35-b8af-5b3a334ac025'	System	19 Nov 2020 17:26:49
User entered 'Yes (Y)'	System	19 Nov 2020 17:26:49

US3552371

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

Please 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 (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-11-19T11:26:33', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'b0f199fb-63ef-4b35-b8af-5b3a334ac025'	System	19 Nov 2020 17:26:49
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Nov 2020 17:26:49

US3552371

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-11-19T11:26:38', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'b0f199fb-63ef-4b35-b8af-5b3a334ac025'	System	19 Nov 2020 17:26:49
User entered '19 Nov 2020 11:26:38'	System	19 Nov 2020 17:26:49

US3552371

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 22:36:24
User entered '15 Nov 2020 00:01'	System	08 Sep 2020 22:36:24

US3552371

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 22:36:24
User entered '19 Nov 2020 23:59'	System	08 Sep 2020 22:36:24

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '05 Nov 2020 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '09 Nov 2020 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '12 Nov 2020 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '16 Nov 2020 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

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 (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-11-22T19:35:42', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '768ceece-6683-47dc-9fa8-7c332a5fc4a1'	System	23 Nov 2020 01:35:56
User entered 'No (N)'	System	23 Nov 2020 01:35:56

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

Have you been exposed to someone with 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 (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-11-22T19:35:45', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '768ceece-6683-47dc-9fa8-7c332a5fc4a1'	System	23 Nov 2020 01:35:56
User entered 'No (N)'	System	23 Nov 2020 01:35:56

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2020-11-22T19:35:52', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '768ceece-6683-47dc-9fa8-7c332a5fc4a1' User entered '22 Nov 2020 19:35:52'	System	23 Nov 2020 01:35:56
	System	23 Nov 2020 01:35:56

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 06:25:08

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:25:08
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 06:25:08

US3552371

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:39:31

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 04:03:35
User entered 'Yes (Y)'	Joan Siegner (b) (4)	28 Sep 2020 13:30:32

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User closed query 'Please update to include elevated liver enzymes ' (Site from CRA).	(b) (4), (b) (6)	24 Oct 2020 23:45:11
User closed query 'Per SC Day 8 , subject experienced headache and fatigue for one day on 14Sep. Please consider adding to AEs. ' (Site from CRA).	(b) (4), (b) (6)	24 Oct 2020 23:45:01
Query 'Please update to include elevated liver enzymes ' answered with 'Updated' (Site from CRA).	Cassandra Zehenny (b) (4)	19 Oct 2020 18:17:34
Query 'Per SC Day 8 , subject experienced headache and fatigue for one day on 14Sep. Please consider adding to AEs. ' answered with '14Sep still part of diary window, reported on day 8 that symptoms had resolved. Thank you!' (Site from CRA).	Cassandra Zehenny (b) (4)	15 Oct 2020 21:47:38
User opened query 'Please update to include elevated liver enzymes ' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 19:46:02
User opened query 'Per SC Day 8 , subject experienced headache and fatigue for one day on 14Sep. Please consider adding to AEs. ' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 19:41:10
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Ankle fracture, LLT: Ankle fracture - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 13:36:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 13:36:47
Data point term sent to Coder	System	28 Sep 2020 13:35:42
User entered 'fractured left ankle'	Joan Siegner (b) (4)	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered 'Yes (Y)'	Joan Siegner (b) (4)	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered 'No (N)'	Joan Siegner (b) (4)	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered 'No (N)'	Joan Siegner (b) (4)	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered '16 Sep 2020'	Joan Siegner (b) (4)	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered empty.	Joan Siegner (b) (4)	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:27:41
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	19 Nov 2020 17:34:05
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Cassandra Zehenny (b) (4)	19 Nov 2020 17:34:05
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered 'Yes (Y)'	Joan Siegner (b) (4)	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:27:43
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	19 Nov 2020 17:34:05
User entered '19 Nov 2020' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Cassandra Zehenny (b) (4)	19 Nov 2020 17:34:05
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered empty.	Joan Siegner (b) (4)	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered empty.	Joan Siegner (b) (4)	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:44:00
DataPoint Un-verified.	Joan Siegner (b) (4)	09 Nov 2020 18:32:14
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Joan Siegner (b) (4)	09 Nov 2020 18:32:14
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered 'Grade 4 (Grade 4)'	Joan Siegner (b) (4)	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 10:53:53
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered with 'Treatment in ER makes this a grade 4; no admission to the hospital; not an SAE' (Site from System).	Joan Siegner (b) (4)	28 Sep 2020 13:36:12
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).		28 Sep 2020 13:35:23
User entered 'No (N)'	Joan Siegner (b) (4)	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered '0'	Joan Siegner (b) (4)	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered '0'	Joan Siegner (b) (4)	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered '0'	Joan Siegner (b) (4)	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered empty.	Joan Siegner (b) (4)	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered empty.	Joan Siegner (b) (4)	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered empty.	Joan Siegner (b) (4)	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered empty.	Joan Siegner (b) (4)	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered '0'	Joan Siegner (b) (4)	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered '0'	Joan Siegner (b) (4)	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered '0'	Joan Siegner (b) (4)	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered 'Not Related (NOT RELATED)'	Joan Siegner (b) (4)	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered 'Not Related (NOT RELATED)'	Joan Siegner (b) (4)	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered 'None (NONE)'	Joan Siegner (b) (4)	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered '0'	Joan Siegner (b) (4)	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered '1'	Joan Siegner (b) (4)	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered '0'	Joan Siegner (b) (4)	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:43:28
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	19 Nov 2020 17:34:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
New Information	Cassandra Zehenny (b) (4)	19 Nov 2020 17:34:05
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Joan Siegner (b) (4)	28 Sep 2020 13:35:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered empty.	Joan Siegner (b) (4)	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered 'Subject fell off a step stool fracturing her left ankle. Treated in ER and released; not admitted to the hospital.'	Joan Siegner (b) (4)	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:39:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User coded data point as SOC: Investigations, HLG: Hepatobiliary investigations, HLT: Liver function analyses, PT: Hepatic enzyme increased, LLT: Elevated liver enzymes - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 18:20:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 18:20:43
Data point term sent to Coder	System	19 Oct 2020 18:19:03
User entered 'Elevated Liver Enzymes'	Cassandra Zehenny (b) (4)	19 Oct 2020 18:18:29

US3552371

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	19 Oct 2020 18:18:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered 'No (N)'	Cassandra Zehenny (b) (4)	19 Oct 2020 18:18:29
	(b) (4)	

US3552371

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	19 Oct 2020 18:18:29

US3552371

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User closed query 'Dosing was disct on 13Oct due to Elevated liver enzymes. Please verify the start date and consider updating to an earlier date. ' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 18:53:26
Query 'Dosing was disct on 13Oct due to Elevated liver enzymes. Please verify the start date and consider updating to an earlier date. ' answered with 'start date is correct' (Site from CRA).	Joan Siegner (b) (4)	30 Oct 2020 16:02:05
User opened query 'Dosing was disct on 13Oct due to Elevated liver enzymes. Please verify the start date and consider updating to an earlier date. ' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 21:00:03
User entered '16 Sep 2020'	Cassandra Zehenny (b) (4)	19 Oct 2020 18:18:29

US3552371

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered empty.	Cassandra Zehenny (b) (4)	19 Oct 2020 18:18:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:18:29

US3552371

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	19 Oct 2020 18:18:29

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered empty.	Cassandra Zehenny (b) (4)	19 Oct 2020 18:18:29
	(b) (4)	

US3552371

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered empty.	Cassandra Zehenny (b) (4)	19 Oct 2020 18:18:29
	(b) (4)	

US3552371

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:18:29

US3552371

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered 'Grade 3/Severe (Grade 3/Severe)'	Cassandra Zehenny (b) (4) (b) (4)	19 Oct 2020 18:18:29

US3552371

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered 'No (N)'	Cassandra Zehenny (b) (4)	19 Oct 2020 18:18:29
	(b) (4)	

US3552371

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered '0'	Cassandra Zehenny (b) (4)	19 Oct 2020 18:18:29
	(b) (4)	

US3552371

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered '0'	Cassandra Zehenny (b) (4)	19 Oct 2020 18:18:29

US3552371

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered '0'	Cassandra Zehenny (b) (4)	19 Oct 2020 18:18:29
	(b) (4)	

US3552371

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered empty.	Cassandra Zehenny (b) (4)	19 Oct 2020 18:18:29
	(b) (4)	

US3552371

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered empty.	Cassandra Zehenny (b) (4)	19 Oct 2020 18:18:29
	(b) (4)	

US3552371

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered empty.	Cassandra Zehenny (b) (4)	19 Oct 2020 18:18:29

US3552371

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered empty.	Cassandra Zehenny (b) (4)	19 Oct 2020 18:18:29
	(b) (4)	

US3552371

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered '0'	Cassandra Zehenny (b) (4)	19 Oct 2020 18:18:29
	(b) (4)	

US3552371

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered '0'	Cassandra Zehenny (b) (4)	19 Oct 2020 18:18:29
	(b) (4)	

US3552371

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered '0'	Cassandra Zehenny (b) (4)	19 Oct 2020 18:18:29
	(b) (4)	

US3552371

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 21:01:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 21:01:27
User entered 'Not Related (NOT RELATED)' reason for change: New Information	Cassandra Zehenny (b) (4)	20 Oct 2020 21:01:27
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 18:18:29
User entered empty.	Cassandra Zehenny (b) (4)	19 Oct 2020 18:18:29

US3552371

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 21:01:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 21:01:27
User entered 'Not Related (NOT RELATED)' reason for change: New Information	Cassandra Zehenny (b) (4)	20 Oct 2020 21:01:27
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 18:18:29
User entered empty.	Cassandra Zehenny (b) (4)	19 Oct 2020 18:18:29

US3552371

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 21:01:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 21:01:27
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: New Information	Cassandra Zehenny (b) (4)	20 Oct 2020 21:01:27
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 18:18:29
User entered empty.	Cassandra Zehenny (b) (4)	19 Oct 2020 18:18:29

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	20 Oct 2020 21:01:27
User entered '1' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	20 Oct 2020 21:01:27
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
User entered '0'	System	19 Oct 2020 18:18:29
	Cassandra Zehenny (b) (4)	19 Oct 2020 18:18:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered '0'	Cassandra Zehenny (b) (4)	19 Oct 2020 18:18:29

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered '0'	Cassandra Zehenny (b) (4)	19 Oct 2020 18:18:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User closed query 'Per CDM Requery: Thank you for the response.Please update the Outcome as Not recovered/not resolved if AE not resolved yet.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 10:14:38
Query 'Per CDM Requery: Thank you for the response.Please update the Outcome as Not recovered/not resolved if AE not resolved yet.' answered with 'done' (Site from DM).	Cassandra Zehenny (b) (4)	02 Nov 2020 17:35:17
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	02 Nov 2020 17:35:13
User opened query 'Per CDM Requery: Thank you for the response.Please update the Outcome as Not recovered/not resolved if AE not resolved yet.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 02:58:19
User closed query 'Per CDM: Outcome is marked as Unknown, however please confirm if the participant is lost to follow up as AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 02:58:19
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Nov 2020 02:56:15
Query 'Data is required. Please complete.' answered with 'AE not resolved yet' (Site from System).	Joan Siegner (b) (4)	30 Oct 2020 16:09:01
Query 'Per CDM: Outcome is marked as Unknown, however please confirm if the participant is lost to follow up as AE is still ongoing.' answered with 'AE not resolved yet' (Site from DM).	Joan Siegner (b) (4)	30 Oct 2020 16:08:52
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 16:08:19
User entered empty; reason for change Data Entry Error	Joan Siegner (b) (4)	30 Oct 2020 16:08:19
User opened query 'Per CDM: Outcome is marked as Unknown, however please confirm if the participant is lost to follow up as AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 12:43:23
User entered 'Unknown (UNKNOWN)'	Cassandra Zehenny (b) (4)	19 Oct 2020 18:18:29

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered empty.	Cassandra Zehenny (b) (4)	19 Oct 2020 18:18:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered empty.	Cassandra Zehenny (b) (4)	19 Oct 2020 18:18:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	19 Oct 2020 18:18:29

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:39:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 18:18:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:01
User entered 'USA-US089-2020-mRNA-1273-P301000012'	System	20 Nov 2020 14:06:36
User entered 'New'	(b) (4), (b) (6)	20 Nov 2020 14:06:36

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:34:59
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Renal and urinary tract neoplasms malignant and unspecified, HLT: Renal neoplasms malignant, PT: Renal cell carcinoma, LLT: Renal cell carcinoma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Nov 2020 12:48:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Nov 2020 12:48:14
Data point term sent to Coder	System	20 Nov 2020 19:44:41
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	20 Nov 2020 19:44:32
Coding entries removed.	Cassandra Zehenny (b) (4) (b) (4)	20 Nov 2020 19:44:32
User entered 'RIGHT kidney renal cell carcinoma' reason for change: New Information	Cassandra Zehenny (b) (4) (b) (4)	20 Nov 2020 19:44:32
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User closed query 'Please add sonogram from 08Oct to concomitant procedures form. ' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 18:54:00
Query 'Please add sonogram from 08Oct to concomitant procedures form. ' answered with 'done' (Site from CRA).	Joan Siegner (b) (4)	30 Oct 2020 16:03:17
User opened query 'Please add sonogram from 08Oct to concomitant procedures form. ' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 21:04:12
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal disorders NEC, PT: Renal mass, LLT: Renal mass - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:03:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:03:36
Data point term sent to Coder	System	20 Oct 2020 21:02:57
User entered 'Right kidney mass'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 21:02:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	20 Oct 2020 21:02:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 21:02:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 21:02:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:34:42
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	20 Nov 2020 17:36:07
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	20 Nov 2020 17:36:07
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:02:57
User entered '8 Oct 2020'	Cassandra Zehenny (b) (4)	20 Oct 2020 21:02:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered empty.	Cassandra Zehenny (b) (4)	20 Oct 2020 21:02:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 21:02:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:34:51
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	20 Nov 2020 17:36:40
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Cassandra Zehenny (b) (4)	20 Nov 2020 17:36:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	20 Oct 2020 21:02:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Please consider updating end date to 13Nov, end of hospitalization, Thank you !' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:17:34
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:17:32
User entered '13 Nov 2020' reason for change: Data Entry Error	Heather Douds (b) (4)	23 Nov 2020 19:49:55
Query 'Please consider updating end date to 13Nov, end of hospitalization, Thank you !' answered with 'Carcinoma removed on 12Nov, not 13 Nov. Still update?' (Site from CRA).	Cassandra Zehenny (b) (4)	23 Nov 2020 15:49:00
User opened query 'Please consider updating end date to 13Nov, end of hospitalization, Thank you !' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 15:34:07
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	20 Nov 2020 17:36:40
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	20 Nov 2020 17:36:40
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	20 Nov 2020 17:36:40
User entered '12 Nov 2020' reason for change: New Information	Cassandra Zehenny (b) (4)	20 Nov 2020 17:36:40
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	20 Nov 2020 17:36:07
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered empty.	Cassandra Zehenny (b) (4)	20 Oct 2020 21:02:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered empty.	Cassandra Zehenny (b) (4)	20 Oct 2020 21:02:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 21:02:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:34:11
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	20 Nov 2020 17:36:40
User entered 'Grade 4 (Grade 4)' reason for change: New Information	(b) (4)	
DataPoint Verified.	Cassandra Zehenny (b) (4)	20 Nov 2020 17:36:40
	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 16:33:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 16:33:54
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: New Information	Cassandra Zehenny (b) (4)	21 Oct 2020 16:33:54
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 21:02:39
User entered empty.	Cassandra Zehenny (b) (4)	20 Oct 2020 21:02:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'Event start date is 08Oct , followed by hospitalization on 12Nov, but it is reported as SAE on 19Nov. Please clarify site awareness date. ' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:18:28
Query 'Event start date is 08Oct , followed by hospitalization on 12Nov, but it is reported as SAE on 19Nov. Please clarify site awareness date. ' answered with 'site was not made aware of situation until 19Nov when calling subject for diary reminder' (Site from CRA).	Cassandra Zehenny (b) (4)	23 Nov 2020 19:42:45
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:34:13
User opened query 'Event start date is 08Oct , followed by hospitalization on 12Nov, but it is reported as SAE on 19Nov. Please clarify site awareness date. ' (Site from CRA).	(b) (4), (b) (6)	22 Nov 2020 16:08:44
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	19 Nov 2020 19:37:14
User entered 'Yes (Y)' reason for change: New Information	Cassandra Zehenny (b) (4)	19 Nov 2020 19:37:14
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 16:33:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 16:33:54
User entered 'No (N)' reason for change: New Information	Cassandra Zehenny (b) (4)	21 Oct 2020 16:33:54
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 21:02:39
User entered empty.	Cassandra Zehenny (b) (4)	20 Oct 2020 21:02:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered '0'	Cassandra Zehenny (b) (4)	20 Oct 2020 21:02:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered '0'	Cassandra Zehenny (b) (4)	20 Oct 2020 21:02:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:34:19
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		19 Nov 2020 19:39:17
Query 'Requires inpatient or prolongation of existing System Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		19 Nov 2020 19:39:17
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	19 Nov 2020 19:37:14
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	19 Nov 2020 19:37:14
User entered '1' reason for change: New Information	(b) (4) Cassandra Zehenny (b) (4)	19 Nov 2020 19:37:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered '0'	Cassandra Zehenny (b) (4)	20 Oct 2020 21:02:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:34:17
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	19 Nov 2020 19:37:14
User entered '12 Nov 2020' reason for change: New Information	(b) (4)	
DataPoint Verified.	Cassandra Zehenny (b) (4)	19 Nov 2020 19:37:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered empty.	Cassandra Zehenny (b) (4)	20 Oct 2020 21:02:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:34:20
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	19 Nov 2020 19:37:14
User entered '13 Nov 2020' reason for change: New Information	(b) (4)	
DataPoint Verified.	Cassandra Zehenny (b) (4)	19 Nov 2020 19:37:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered empty.	Cassandra Zehenny (b) (4)	20 Oct 2020 21:02:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:34:22
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	19 Nov 2020 19:39:17
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Cassandra Zehenny (b) (4)	19 Nov 2020 19:39:17
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered empty.	Cassandra Zehenny (b) (4)	20 Oct 2020 21:02:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered empty.	Cassandra Zehenny (b) (4)	20 Oct 2020 21:02:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered '0'	Cassandra Zehenny (b) (4)	20 Oct 2020 21:02:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered '0'	Cassandra Zehenny (b) (4)	20 Oct 2020 21:02:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered '0'	Cassandra Zehenny (b) (4)	20 Oct 2020 21:02:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4)	20 Oct 2020 21:02:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 21:02:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:18:34
DataPoint Un-verified.	Stanley Doublin (b) (4)	23 Nov 2020 17:55:52
User entered 'None (NONE)' reason for change:	Stanley Doublin (b) (4)	23 Nov 2020 17:55:52
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered 'Not Applicable (NOT APPLICABLE)'	Cassandra Zehenny (b) (4)	20 Oct 2020 21:02:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:34:26
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).		20 Nov 2020 17:37:01
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	20 Nov 2020 17:37:01
User entered '0' reason for change: New Information	(b) (4)	
	Cassandra Zehenny (b) (4)	20 Nov 2020 17:37:01
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4)	
	System	20 Nov 2020 17:36:07
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered '1'	Cassandra Zehenny (b) (4)	20 Oct 2020 21:02:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:34:27
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	20 Nov 2020 17:37:19
User entered '1' reason for change: New Information	(b) (4) Cassandra Zehenny (b) (4)	20 Nov 2020 17:37:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 21:02:39

US3552371

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:34:29
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	20 Nov 2020 17:36:07
User entered '1' reason for change: New Information	(b) (4) Cassandra Zehenny (b) (4)	20 Nov 2020 17:36:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 21:02:39

US3552371

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:34:30
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	20 Nov 2020 17:36:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Cassandra Zehenny (b) (4)	20 Nov 2020 17:36:07
New Information	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User closed query 'Per CDM Requery: Per CCG page 38, data to be entered for Outcome. Please update the Outcome.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 10:15:07
Query 'Per CDM Requery: Per CCG page 38, data to be entered for Outcome. Please update the Outcome.' answered with 'done' (Site from DM).	Cassandra Zehenny (b) (4)	02 Nov 2020 17:36:37
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	02 Nov 2020 17:36:31
User opened query 'Per CDM Requery: Per CCG page 38, data to be entered for Outcome. Please update the Outcome.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 02:55:44
User closed query 'Per CDM: Outcome is marked as Unknown, however please confirm if the participant is lost to follow up as AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 02:55:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Nov 2020 02:51:59
Query 'Data is required. Please complete.' answered with 'AE ongoing' (Site from System).	Joan Siegner (b) (4)	30 Oct 2020 16:09:49
Query 'Per CDM: Outcome is marked as Unknown, however please confirm if the participant is lost to follow up as AE is still ongoing.' answered with 'AE ongoing' (Site from DM).	Joan Siegner (b) (4)	30 Oct 2020 16:09:47
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 16:09:33
User entered empty; reason for change Data Entry Error	Joan Siegner (b) (4)	30 Oct 2020 16:09:33

US3552371

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Outcome is marked as Unknown, however please confirm if the participant is lost to follow up as AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 12:43:46
User entered 'Unknown (UNKNOWN)'	Cassandra Zehenny (b) (4)	20 Oct 2020 21:02:39

US3552371

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered empty.	Cassandra Zehenny (b) (4)	20 Oct 2020 21:02:39
	(b) (4)	

US3552371

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:18:44
DataPoint Un-verified.	Heather Douds (b) (4)	23 Nov 2020 19:50:55
User entered 'RENAL MASS FOUND ON ULTRASOUND BY HAPPENSTANCE AFTER ANKLE FRACTURE. MASS FOUND TO BE RENAL CELL CARCINOMA. SUBJECT NOTIFIED US THAT SHE HAD PARTIAL NEPHRECTOMY OF HER RIGHT KIDNEY TO REMOVE RENAL MASS ON 12NOV. SURGERY COMPLETED AND PATIENT HAS RECOVERED. Discharged from hospital on 13NOV.' reason for change: New Information	Heather Douds (b) (4)	23 Nov 2020 19:50:55
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:34:33
User entered 'renal mass found on ultrasound by happenstance after ankle fracture. mass found to be renal cell carcinoma. SUBJECT NOTIFIED US THAT SHE HAD PARTIAL NEPHRECTOMY OF HER RIGHT KIDNEY TO REMOVE RENAL MASS ON 12NOV. SURGERY COMPLETED AND PATIENT HAS RECOVERED.' reason for change: New Information	Cassandra Zehenny (b) (4)	20 Nov 2020 19:30:02
User entered 'SUBJECT NOTIFIED US THAT SHE HAD partial nephrectomy of her RIGHT KIDNEY to remove renal MASS ON 12NOV. Surgery completed and patient has recovered.' reason for change: New Information	Cassandra Zehenny (b) (4)	20 Nov 2020 17:36:07
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	19 Nov 2020 19:37:14
User entered 'Subject notified us that she had right kidney mass removed on 12Nov. Medical records requested, will update when we receive further information' reason for change: New Information	Cassandra Zehenny (b) (4)	19 Nov 2020 19:37:14
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered empty.	Cassandra Zehenny (b) (4)	20 Oct 2020 21:02:39

US3552371

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 19:37:14
User entered '0'	System	21 Oct 2020 16:33:54

US3552371

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:02:39

US3552371

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:39:31

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 19:39:17

US3552371

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:06:44
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 16:46:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 16:46:36
Data point term sent to Coder	System	27 Oct 2020 16:45:49
User entered 'anxiety'	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:45:29

US3552371

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:06:45
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:45:29

US3552371

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:06:47
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:45:29

US3552371

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:06:48
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:45:29

US3552371

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:06:42
User entered '22 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:45:29

US3552371

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:45:29

US3552371

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 16:45:29

US3552371

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:31:23
User entered 'No (N)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	03 Nov 2020 16:27:05
User entered 'Yes (Y)'	Mikayla Frye (b) (4)	27 Oct 2020 16:45:29

US3552371

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:31:24
User entered '29 Oct 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4)	03 Nov 2020 16:27:05
User entered empty.	(b) (4)	
	Mikayla Frye (b) (4)	27 Oct 2020 16:45:29
	(b) (4)	

US3552371

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:31:26
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:45:29

US3552371

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 16:45:29

US3552371

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:31:28
User entered 'Grade 1/Mild (Grade 1/Mild)'	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:45:29

US3552371

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:31:30
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:45:29

US3552371

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:31:31
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:45:29

US3552371

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:31:37
User entered '0'	Mikayla Frye (b) (4)	27 Oct 2020 16:45:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:31:38
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:45:29

US3552371

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:31:40
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:45:29

US3552371

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:31:41
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:45:29

US3552371

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:31:42
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:45:29

US3552371

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:31:44
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:45:29

US3552371

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:31:45
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:45:29

US3552371

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:31:47
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:45:29

US3552371

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:31:48
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:45:29

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:31:50
User entered 'Not Related (NOT RELATED)'	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:45:29

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:31:51
User entered 'Not Related (NOT RELATED)'	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:45:29

US3552371

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:18:56
DataPoint Un-verified.	Stanley Doublin (b) (4)	23 Nov 2020 17:56:49
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	23 Nov 2020 17:56:49
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:31:53
User entered 'None (NONE)'	Mikayla Frye (b) (4)	27 Oct 2020 16:45:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:31:55
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:45:29

US3552371

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:31:56
User entered '1'	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:45:29

US3552371

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:31:58
User entered '0'	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:45:29

US3552371

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:31:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	03 Nov 2020 16:27:05
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mikayla Frye (b) (4)	27 Oct 2020 16:45:29

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:32:01
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:45:29

US3552371

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:32:03
User entered empty.	Mikayla Frye (b) (4) (b) (4)	27 Oct 2020 16:45:29

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	27 Oct 2020 16:45:29

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:39:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:45:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:39:31

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 04:03:57
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:35:30

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:39:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
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)	09 Sep 2020 20:37:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 20:37:57
Data point term sent to Coder	System	09 Sep 2020 20:36:48
User entered 'atorvastatin'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:36:12

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:39:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:36:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:39:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'hyperlipidemia'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:36:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:39:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered '10'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:36:12

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:39:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:36:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:39:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:36:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:39:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:36:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:39:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:36:12

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:39:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:36:12

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:39:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:36:12

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'un Oct 2018'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:36:12

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered '0'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:36:12

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:39:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'No (N)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	29 Sep 2020 16:54:49
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	09 Sep 2020 20:36:12

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:39:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered '24 Sep 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4)	29 Sep 2020 16:54:49
User entered empty.	Stanley Doublin (b) (4)	09 Sep 2020 20:36:12

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:39:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:36:12

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:39:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 20:36:12

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:39:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 20:36:12

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:39:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 20:36:12

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:39:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 20:38:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 20:38:53
Data point term sent to Coder	System	09 Sep 2020 20:37:52
User entered 'levothyroxine'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:37:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:39:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:37:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:39:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'hypothyroid'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:37:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:39:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 08:54:33
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	08 Oct 2020 21:41:58
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:19:34
User entered '.88'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:37:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:39:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	19 Nov 2020 15:35:54
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	19 Nov 2020 15:35:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'Other (OTHER)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	08 Oct 2020 21:41:53
	(b) (4)	
User entered 'mg (mg)'	Stanley Doublin (b) (4)	09 Sep 2020 20:37:13
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:39:31

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User closed query 'Per CDM: The dose unit other specify is mentioned as "MCG" which is one of the listed choices of the dose unit "ug". Kindly select the appropriate drop down and make other specify as blank.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 03:46:17
Query 'Per CDM: The dose unit other specify is mentioned as "MCG" which is one of the listed choices of the dose unit "ug". Kindly select the appropriate drop down and make other specify as blank.' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	19 Nov 2020 15:36:02
DataPoint Un-verified.	(b) (4)	
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4)	19 Nov 2020 15:35:54
User opened query 'Per CDM: The dose unit other specify is mentioned as "MCG" which is one of the listed choices of the dose unit "ug". Kindly select the appropriate drop down and make other specify as blank.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 11:33:37
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'mcg' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	08 Oct 2020 21:41:53
User entered empty.	Stanley Dublin (b) (4)	09 Sep 2020 20:37:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:39:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:37:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:39:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:37:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:39:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:37:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:39:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:37:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'un May 1995'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:37:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered '0'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:37:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:39:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:37:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:39:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:37:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:39:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:37:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:39:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 20:37:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:39:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 20:37:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:39:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 20:37:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:39:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 20:39:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 20:39:47
Data point term sent to Coder	System	09 Sep 2020 20:38:54
User entered 'vitamin d3'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:38:08

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:39:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:06:16
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4)	
	Cassandra Zehenny (b) (4)	11 Nov 2020 17:06:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'No (N)'	Stanley Doublin (b) (4)	09 Sep 2020 20:38:08
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:39:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'health promotion'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:38:08

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:39:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 10:34:27
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'Subject reported data, exact dosage unknown. Thank you.' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	08 Oct 2020 21:42:16
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:19:43
User entered '1'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:38:08

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:39:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'tablet (TABLET)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:38:08

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:39:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:38:08

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:39:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:38:08

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:39:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:38:08

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:39:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:38:08

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:39:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:38:08

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'un Sep 2017'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:38:08

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered '0'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:38:08

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:39:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:38:08

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:39:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:38:08

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:39:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:38:08

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:39:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 20:38:08

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:39:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 20:38:08

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:39:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 20:38:08

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:39:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 20:40:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 20:40:56
Data point term sent to Coder	System	09 Sep 2020 20:39:56
User entered 'magnesium'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:38:59

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:39:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:06:22
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4)	
	Cassandra Zehenny (b) (4)	11 Nov 2020 17:06:22
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'No (N)'	Stanley Doublin (b) (4)	09 Sep 2020 20:38:59
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:39:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'health promotion'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:38:59

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:39:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 10:34:32
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'Subject reported data, exact dosage unknown. Thank you.' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	08 Oct 2020 21:42:21
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:19:56
User entered '1'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:38:59

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:39:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'tablet (TABLET)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:38:59

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:39:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:38:59

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:39:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:38:59

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:39:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:38:59

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:39:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:38:59

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:39:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:38:59

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'un Sep 2017'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:38:59

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered '0'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:38:59

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:39:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:38:59

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:39:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:38:59

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:39:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:38:59

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:39:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 20:38:59

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:39:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 20:38:59

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:39:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 20:38:59

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:39:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 20:40:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 20:40:56
Data point term sent to Coder	System	09 Sep 2020 20:39:58
User entered 'zinc'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:39:37

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:39:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:06:38
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4)	
	Cassandra Zehenny (b) (4)	11 Nov 2020 17:06:38
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'No (N)'	Stanley Doublin (b) (4)	09 Sep 2020 20:39:37
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:39:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'health promotion'	Stanley Dublin (b) (4) (b) (4)	09 Sep 2020 20:39:37

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:39:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 10:34:37
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'Subject reported data, exact dosage unknown. Thank you.' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	08 Oct 2020 21:42:25
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:20:06
User entered '1'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:39:37

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:39:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'tablet (TABLET)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:39:37

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:39:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:39:37

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:39:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:39:37

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:39:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:39:37

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:39:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:39:37

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:39:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:39:37

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'un Sep 2017'	Stanley Dublin (b) (4) (b) (4)	09 Sep 2020 20:39:37

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered '0'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:39:37

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:39:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:39:37

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:39:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:39:37

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:39:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:39:37

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:39:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 20:39:37

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:39:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 20:39:37

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:39:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 20:39:37

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:39:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 21:24:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 21:24:44
Data point term sent to Coder	System	09 Sep 2020 21:23:16
Data point term sent to Coder	System	09 Sep 2020 20:41:01
User entered 'advil'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:40:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:39:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:40:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:39:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'muscle soreness' reason for change: Data Entry Error	Joan Siegner (b) (4)	09 Sep 2020 21:22:48
User entered 'health promotion'	Stanley Dublin (b) (4)	09 Sep 2020 20:40:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:39:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 10:34:45
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'Subject reported data, exact dosage unknown. Thank you.' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	08 Oct 2020 21:42:42
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:20:16
User entered '2'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:40:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:39:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'tablet (TABLET)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:40:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:39:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:40:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:39:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'as needed (PRN)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:40:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:39:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:40:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:39:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:40:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:39:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:40:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'un UNK 1995'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:40:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered '0'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:40:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:39:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:40:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:39:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered '05 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:40:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:39:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:40:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:39:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 20:40:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:39:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 20:40:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:39:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 20:40:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:39:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 00:11:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 00:11:39
Data point term sent to Coder	System	29 Sep 2020 16:48:25
User entered 'percocet [oxycodone and acetaminophen]'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:47:51

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:39:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:47:51

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:39:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'fractured ankle'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:47:51

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:39:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered '5/325'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:47:51

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:39:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:47:51

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:39:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:47:51

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:39:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'as needed (PRN)'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:47:51

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:39:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:47:51

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:39:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:47:51

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:39:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:47:51

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered '16 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:47:51

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered '0'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:47:51

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:39:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:47:51

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:39:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered '21 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:47:51

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:39:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:47:51

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:39:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 16:47:51

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:39:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 16:47:51

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:39:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 16:47:51

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:39:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
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)	29 Sep 2020 17:27:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 17:27:37
Data point term sent to Coder	System	29 Sep 2020 16:53:39
User entered 'gabapentin'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:53:29

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:39:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:53:29

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:39:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'fractured ankle'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:53:29

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:39:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered '100'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:53:29

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:39:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:53:29

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:39:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:53:29

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:39:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'three times daily (TID)'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:53:29

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:39:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:53:29

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:39:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:53:29

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:39:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:53:29

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered '16 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:53:29

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered '0'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:53:29

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:39:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:53:29

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:39:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered '21 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:53:29

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:39:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:53:29

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:39:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	29 Sep 2020 16:53:29

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:39:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 16:53:29

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:39:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 16:53:29

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:39:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
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)	29 Sep 2020 22:57:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 22:57:44
Data point term sent to Coder	System	29 Sep 2020 16:54:41
User entered 'calcium supplenment'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:54:24

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:39:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:06:57
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4)	
	Cassandra Zehenny (b) (4)	11 Nov 2020 17:06:57
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'No (N)'	Stanley Doublin (b) (4)	29 Sep 2020 16:54:24
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:39:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'health'	Stanley Dublin (b) (4) (b) (4)	29 Sep 2020 16:54:24

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:39:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered '500'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:54:24

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:39:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'IU (IU)'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:54:24

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:39:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:54:24

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:39:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:54:24

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:39:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:54:24

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:39:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:54:24

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:39:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:54:24

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'un UNK 2018'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:54:24

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered '0'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:54:24

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:39:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:54:24

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:39:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered '21 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:54:24

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:39:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	29 Sep 2020 16:54:24

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:39:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 16:54:24

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:39:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 16:54:24

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:39:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 16:54:24

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:39:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:05:08
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 15:21:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	27 Oct 2020 15:21:43
Data point term sent to Coder	System	27 Oct 2020 15:21:12
User entered 'influenza vaccine'	Stanley Doublin (b) (4)	27 Oct 2020 15:20:42
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:39:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:05:09
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	27 Oct 2020 15:20:42

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:39:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:05:11
User entered 'prophylaxis'	Stanley Doublin (b) (4) (b) (4)	27 Oct 2020 15:20:42

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:39:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:44
User entered '1'	Stanley Doublin (b) (4) (b) (4)	27 Oct 2020 15:20:42

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:39:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:45
User entered 'Other (OTHER)'	Stanley Doublin (b) (4) (b) (4)	27 Oct 2020 15:20:42

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:39:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:47
User entered 'injection'	Stanley Doublin (b) (4) (b) (4)	27 Oct 2020 15:20:42

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:39:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:48
User entered 'once (ONCE)'	Stanley Doublin (b) (4) (b) (4)	27 Oct 2020 15:20:42

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:39:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:43:19
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Oct 2020 15:20:42

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:39:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:43:21
User entered 'Intramuscular (INTRAMUSCULAR)'	Stanley Doublin (b) (4) (b) (4)	27 Oct 2020 15:20:42

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:39:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:43:23
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Oct 2020 15:20:42

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:05:12
User entered '22 Oct 2020'	Stanley Doublin (b) (4) (b) (4)	27 Oct 2020 15:20:42

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:43:25
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Oct 2020 15:20:42

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:39:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:43:27
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	27 Oct 2020 15:20:42

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:39:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:43:30
User entered '22 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	27 Oct 2020 15:20:42

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:39:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:43:32
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	27 Oct 2020 15:20:42

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:39:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 15:20:42

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:39:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 15:20:42

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:39:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 15:20:42

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:39:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM OXALATE, PRODUCTSYNONYM: LEXAPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 15:23:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 15:23:42
Data point term sent to Coder	System	27 Oct 2020 15:22:12
User entered 'lexapro'	Stanley Doublin (b) (4)	27 Oct 2020 15:21:26

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:39:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:09
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	27 Oct 2020 15:21:26

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:39:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:11
User entered 'anxiety'	Stanley Dublin (b) (4) (b) (4)	27 Oct 2020 15:21:26

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:39:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:12
User entered '10'	Stanley Doublin (b) (4) (b) (4)	27 Oct 2020 15:21:26

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:39:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:14
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	27 Oct 2020 15:21:26

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:39:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:16
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Oct 2020 15:21:26

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:39:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:17
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	27 Oct 2020 15:21:26

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:39:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:19
User entered empty.	Stanley Doublin (b) (4) (b) (4)	27 Oct 2020 15:21:26

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:39:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:21
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4) (b) (4)	27 Oct 2020 15:21:26

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:39:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:22
User entered empty.	Stanley Dublin (b) (4) (b) (4)	27 Oct 2020 15:21:26

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:24
User entered '22 Oct 2020'	Stanley Doublin (b) (4) (b) (4)	27 Oct 2020 15:21:26

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:26
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Oct 2020 15:21:26

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:39:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:27
User entered 'Yes (Y)' reason for change: Data Entry Error	Joan Siegner (b) (4)	27 Oct 2020 15:29:27
User entered 'No (N)'	Stanley Dublin (b) (4)	27 Oct 2020 15:21:26

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:39:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:29
User entered empty; reason for change Data Entry Error	Joan Siegner (b) (4)	27 Oct 2020 15:29:27
User entered '22 Oct 2020'	Stanley Dublin (b) (4)	27 Oct 2020 15:21:26

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:39:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:44:30
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	27 Oct 2020 15:21:26

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:39:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 15:21:26

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:39:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 15:21:26

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:39:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 15:21:26

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:39:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:06:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:06:02
Data point term sent to Coder	System	20 Nov 2020 17:52:22
User entered 'Percocet [Oxycodone-Acetaminophen]	Cassandra Zehenny (b) (4) (b) (4)	20 Nov 2020 17:51:53

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:39:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered 'No (N)'	Cassandra Zehenny (b) (4)	20 Nov 2020 17:51:53

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:39:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered 'partial nephrectomy pain'	Cassandra Zehenny (b) (4) (b) (4)	20 Nov 2020 17:51:53

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:39:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered '5-325'	Cassandra Zehenny (b) (4) (b) (4)	20 Nov 2020 17:51:53

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:39:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered 'mg (mg)'	Cassandra Zehenny (b) (4) (b) (4)	20 Nov 2020 17:51:53

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:39:31

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered empty.	Cassandra Zehenny (b) (4)	20 Nov 2020 17:51:53
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:39:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered 'as needed (PRN)'	Cassandra Zehenny (b) (4)	20 Nov 2020 17:51:53

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:39:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered empty.	Cassandra Zehenny (b) (4)	20 Nov 2020 17:51:53

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:39:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered 'Oral (ORAL)'	Cassandra Zehenny (b) (4)	20 Nov 2020 17:51:53

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:39:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	20 Nov 2020 17:51:53

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered '13 Nov 2020'	Cassandra Zehenny (b) (4)	20 Nov 2020 17:51:53
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	20 Nov 2020 17:51:53

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:39:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 17:51:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 17:51:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	20 Nov 2020 17:51:59
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 17:51:53
User entered empty.	Cassandra Zehenny (b) (4)	20 Nov 2020 17:51:53

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:39:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered empty.	Cassandra Zehenny (b) (4)	20 Nov 2020 17:51:53
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:39:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered 'No (N)'	Cassandra Zehenny (b) (4)	20 Nov 2020 17:51:53

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:39:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 17:51:53

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:39:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 17:51:53

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:39:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 17:51:53

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:39:31

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'CDM-Coding: Please update the term to include the active ingredient name(s) in brackets next to the drug to enable coding.' (Site from System).	Coder Import (b) (4)	25 Nov 2020 05:10:02
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
Data point term sent to Coder	System	20 Nov 2020 17:53:23
User entered 'Crystalloid Fluids'	Cassandra Zehenny (b) (4)	20 Nov 2020 17:53:07
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:39:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered 'No (N)'	Cassandra Zehenny (b) (4)	20 Nov 2020 17:53:07

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:39:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered 'Intra-Op fluids'	Cassandra Zehenny (b) (4)	20 Nov 2020 17:53:07

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:39:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered '2500'	Cassandra Zehenny (b) (4) (b) (4)	20 Nov 2020 17:53:07

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:39:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered 'mL (mL)'	Cassandra Zehenny (b) (4)	20 Nov 2020 17:53:07
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:39:31

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered empty.	Cassandra Zehenny (b) (4)	20 Nov 2020 17:53:07
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:39:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered 'other (OTHER)'	Cassandra Zehenny (b) (4)	20 Nov 2020 17:53:07

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:39:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered 'continuous'	Cassandra Zehenny (b) (4)	20 Nov 2020 17:53:07

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:39:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered 'Intravenous (INTRAVENOUS)'	Cassandra Zehenny (b) (4) (b) (4)	20 Nov 2020 17:53:07

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:39:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered empty.	Cassandra Zehenny (b) (4)	20 Nov 2020 17:53:07
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered '12 Nov 2020'	Cassandra Zehenny (b) (4)	20 Nov 2020 17:53:07

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered '0'	Cassandra Zehenny (b) (4)	20 Nov 2020 17:53:07

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:39:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered 'No (N)'	Cassandra Zehenny (b) (4)	20 Nov 2020 17:53:07

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:39:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered '13 Nov 2020'	Cassandra Zehenny (b) (4)	20 Nov 2020 17:53:07
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:39:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered 'No (N)'	Cassandra Zehenny (b) (4)	20 Nov 2020 17:53:07

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:39:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 17:53:07

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:39:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 17:53:07

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:39:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 17:53:07

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:39:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:06:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:06:05
Data point term sent to Coder	System	20 Nov 2020 17:57:28
User entered 'Morphine Patient controlled analgesic'	Cassandra Zehenny (b) (4) (b) (4)	20 Nov 2020 17:56:40

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:39:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered 'No (N)'	Cassandra Zehenny (b) (4)	20 Nov 2020 17:56:40

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:39:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered 'partial nephrectomy pain'	Cassandra Zehenny (b) (4) (b) (4)	20 Nov 2020 17:56:40

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:39:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered '30/3'	Cassandra Zehenny (b) (4) (b) (4)	20 Nov 2020 17:56:40

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:39:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered 'Other (OTHER)'	Cassandra Zehenny (b) (4)	20 Nov 2020 17:56:40

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:39:31

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered 'mg/mL'	Cassandra Zehenny (b) (4)	20 Nov 2020 17:56:40
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:39:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered 'as needed (PRN)'	Cassandra Zehenny (b) (4)	20 Nov 2020 17:56:40

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:39:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered empty.	Cassandra Zehenny (b) (4)	20 Nov 2020 17:56:40

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:39:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered 'Intravenous (INTRAVENOUS)'	Cassandra Zehenny (b) (4) (b) (4)	20 Nov 2020 17:56:40

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:39:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered empty.	Cassandra Zehenny (b) (4)	20 Nov 2020 17:56:40
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:39:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered '12 Nov 2020'	Cassandra Zehenny (b) (4)	20 Nov 2020 17:56:40

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered '0'	Cassandra Zehenny (b) (4)	20 Nov 2020 17:56:40

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:39:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered 'No (N)'	Cassandra Zehenny (b) (4)	20 Nov 2020 17:56:40

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:39:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered '13 Nov 2020'	Cassandra Zehenny (b) (4)	20 Nov 2020 17:56:40

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:39:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	20 Nov 2020 17:56:40

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:39:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 17:56:40

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:39:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 17:56:40

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:39:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 17:56:40

US3552371

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:39:31

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:08
User entered 'Yes (Y)'	Joan Siegner (b) (4)	30 Oct 2020 16:03:24

US3552371

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:39:31

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:38:01
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	20 Nov 2020 17:34:09
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	20 Nov 2020 17:34:09
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:50
User entered '8 Oct 2020'	Joan Siegner (b) (4)	30 Oct 2020 16:03:45

US3552371

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:39:31

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:52
User entered 'abdominal ultrasound'	Joan Siegner (b) (4)	30 Oct 2020 16:03:45

US3552371

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:39:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:54
User entered 'Adverse Event (AE)'	Joan Siegner (b) (4)	30 Oct 2020 16:03:45

US3552371

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:39:31

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:55
User entered empty.	Joan Siegner (b) (4)	30 Oct 2020 16:03:45

US3552371

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:39:31

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:38:11
User entered '12 Nov 2020'	Cassandra Zehenny (b) (4)	20 Nov 2020 17:34:30

US3552371

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:39:31

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:38:12
User entered 'Partial nephrectomy of right kidney'	Cassandra Zehenny (b) (4) (b) (4)	20 Nov 2020 17:34:30

US3552371

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:39:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:38:13
User entered 'Adverse Event (AE)'	Cassandra Zehenny (b) (4)	20 Nov 2020 17:34:30

US3552371

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:39:31

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:38:15
User entered empty.	Cassandra Zehenny (b) (4)	20 Nov 2020 17:34:30
	(b) (4)	

US3552371

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:39:31

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:54:58
User entered '13 Oct 2020'	Cassandra Zehenny (b) (4)	15 Oct 2020 20:32:10
	(b) (4)	

US3552371

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:39:31

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:55:00
User entered 'AE (specify) (ADVERSE EVENT)'	Cassandra Zehenny (b) (4) (b) (4)	15 Oct 2020 20:32:10

US3552371

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:39:31

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 instead of details ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	22 Nov 2020 23:32:25
	(b) (4), (b) (6)	18 Nov 2020 20:14:16
Query 'Per CDM: Please record AE record number instead of details ' answered with 'updated' (Site from DM). DataPoint Un-verified.	Cassandra Zehenny (b) (4)	18 Nov 2020 17:44:45
	(b) (4)	
	Cassandra Zehenny (b) (4)	18 Nov 2020 17:44:42
	(b) (4)	
User entered 'AE #2' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	18 Nov 2020 17:44:42
	(b) (4)	
User opened query 'Per CDM: Please record AE record number instead of details ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:18:00
	(b) (4), (b) (6)	28 Oct 2020 20:55:01
User entered 'ELEVATED LIVER ENZYMES' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	15 Oct 2020 20:32:24
	(b) (4)	
User entered 'Elevated liver enzyme'	Cassandra Zehenny (b) (4)	15 Oct 2020 20:32:10
	(b) (4)	

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'USA-US089-2020-MRNA-1273-P301000012'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'Yes (Y)'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'No (N)'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'No (N)'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'Yes (Y)'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'No (N)'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'No (N)'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'No (N)'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'sharon'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'frey'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

Site Address: [Street](#)

Audit	User	Time (GMT)
Un-reviewed for Safety.	System	24 Nov 2020 12:46:20
DataPoint Un-verified.	System	24 Nov 2020 12:46:20
User entered empty.	System	24 Nov 2020 12:46:20
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 12:46:11
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:19:17
User closed query 'Please enter site's address information ' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:19:15
Query 'Please enter site's address information ' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4)	23 Nov 2020 15:48:01
	(b) (4)	
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	23 Nov 2020 15:47:56
	(b) (4)	
User opened query 'Please enter site's address information ' (Site from CRA).	(b) (4), (b) (6)	22 Nov 2020 16:06:50

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

Site Address: [City](#)

Audit	User	Time (GMT)
Un-reviewed for Safety.	System	24 Nov 2020 12:46:20
DataPoint Un-verified.	System	24 Nov 2020 12:46:20
User entered empty.	System	24 Nov 2020 12:46:20
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 12:46:11
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:19:18
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	23 Nov 2020 15:47:56
	(b) (4)	

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Site Address:](#) [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'MO'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Un-reviewed for Safety.	System	24 Nov 2020 12:46:20
DataPoint Un-verified.	System	24 Nov 2020 12:46:20
User entered empty.	System	24 Nov 2020 12:46:20
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 12:46:11
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:19:19
User entered '63104'	Cassandra Zehenny (b) (4)	23 Nov 2020 15:47:56
	(b) (4)	

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 14:49:12
User entered 'US'	System	20 Nov 2020 14:06:52

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	24 Nov 2020 12:46:20
User entered '2'	System	23 Nov 2020 14:49:26
User entered '1'	System	20 Nov 2020 14:06:52

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'USA-US089-2020-MRNA-1273-P301000012'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'Yes (Y)'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'No (N)'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'No (N)'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'Yes (Y)'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'No (N)'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'No (N)'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'No (N)'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'sharon'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'frey'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

Site Address: [Street](#)

Audit	User	Time (GMT)
Un-reviewed for Safety.	System	24 Nov 2020 12:46:20
DataPoint Un-verified.	System	24 Nov 2020 12:46:20
User entered empty.	System	24 Nov 2020 12:46:20
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 12:46:11
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:19:17
User closed query 'Please enter site's address information ' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:19:15
Query 'Please enter site's address information ' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4)	23 Nov 2020 15:48:01
	(b) (4)	
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	23 Nov 2020 15:47:56
	(b) (4)	
User opened query 'Please enter site's address information ' (Site from CRA).	(b) (4), (b) (6)	22 Nov 2020 16:06:50

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

Site Address: [City](#)

Audit	User	Time (GMT)
Un-reviewed for Safety.	System	24 Nov 2020 12:46:20
DataPoint Un-verified.	System	24 Nov 2020 12:46:20
User entered empty.	System	24 Nov 2020 12:46:20
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 12:46:11
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:19:18
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	23 Nov 2020 15:47:56
	(b) (4)	

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'MO'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Un-reviewed for Safety.	System	24 Nov 2020 12:46:20
DataPoint Un-verified.	System	24 Nov 2020 12:46:20
User entered empty.	System	24 Nov 2020 12:46:20
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 12:46:11
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:19:19
User entered '63104'	Cassandra Zehenny (b) (4)	23 Nov 2020 15:47:56
	(b) (4)	

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 14:49:12
User entered 'US'	System	20 Nov 2020 14:06:52

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	24 Nov 2020 12:46:20
User entered '2'	System	23 Nov 2020 14:49:26
User entered '1'	System	20 Nov 2020 14:06:52

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:39:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
User entered '20/Nov/2020 14:06'	System	20 Nov 2020 14:06:52

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:39:31

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 14:49:12
User entered '1'	(b) (4), (b) (6)	20 Nov 2020 14:06:52

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'USA-US089-2020-MRNA-1273-P301000012'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'Yes (Y)'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'No (N)'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'No (N)'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'Yes (Y)'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'No (N)'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'No (N)'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'No (N)'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'sharon'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'frey'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

Site Address: [Street](#)

Audit	User	Time (GMT)
Un-reviewed for Safety.	System	24 Nov 2020 12:46:20
DataPoint Un-verified.	System	24 Nov 2020 12:46:20
User entered empty.	System	24 Nov 2020 12:46:20
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 12:46:11
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:19:17
User closed query 'Please enter site's address information ' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:19:15
Query 'Please enter site's address information ' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4)	23 Nov 2020 15:48:01
	(b) (4)	
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	23 Nov 2020 15:47:56
	(b) (4)	
User opened query 'Please enter site's address information ' (Site from CRA).	(b) (4), (b) (6)	22 Nov 2020 16:06:50

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

Site Address: [City](#)

Audit	User	Time (GMT)
Un-reviewed for Safety.	System	24 Nov 2020 12:46:20
DataPoint Un-verified.	System	24 Nov 2020 12:46:20
User entered empty.	System	24 Nov 2020 12:46:20
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 12:46:11
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:19:18
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	23 Nov 2020 15:47:56
	(b) (4)	

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Site Address:](#) [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'MO'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Un-reviewed for Safety.	System	24 Nov 2020 12:46:20
DataPoint Un-verified.	System	24 Nov 2020 12:46:20
User entered empty.	System	24 Nov 2020 12:46:20
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 12:46:11
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:19:19
User entered '63104'	Cassandra Zehenny (b) (4)	23 Nov 2020 15:47:56
	(b) (4)	

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 14:49:12
User entered 'US'	System	20 Nov 2020 14:06:52

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	24 Nov 2020 12:46:20
User entered '2'	System	23 Nov 2020 14:49:26
User entered '1'	System	20 Nov 2020 14:06:52

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:39:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
User entered '23/Nov/2020 09:49'	System	23 Nov 2020 14:49:26

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:39:31

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.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 12:46:11
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
User entered '1'	(b) (4), (b) (6)	23 Nov 2020 14:49:26

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'USA-US089-2020-MRNA-1273-P301000012'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'Yes (Y)'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'No (N)'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'No (N)'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'Yes (Y)'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'No (N)'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'No (N)'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'No (N)'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'sharon'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'frey'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

Site Address: [Street](#)

Audit	User	Time (GMT)
Un-reviewed for Safety.	System	24 Nov 2020 12:46:20
DataPoint Un-verified.	System	24 Nov 2020 12:46:20
User entered empty.	System	24 Nov 2020 12:46:20
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 12:46:11
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:19:17
User closed query 'Please enter site's address information ' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:19:15
Query 'Please enter site's address information ' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4)	23 Nov 2020 15:48:01
	(b) (4)	
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	23 Nov 2020 15:47:56
	(b) (4)	
User opened query 'Please enter site's address information ' (Site from CRA).	(b) (4), (b) (6)	22 Nov 2020 16:06:50

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

Site Address: [City](#)

Audit	User	Time (GMT)
Un-reviewed for Safety.	System	24 Nov 2020 12:46:20
DataPoint Un-verified.	System	24 Nov 2020 12:46:20
User entered empty.	System	24 Nov 2020 12:46:20
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 12:46:11
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:19:18
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	23 Nov 2020 15:47:56
	(b) (4)	

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Site Address:](#) [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:06:46
User entered 'MO'	System	20 Nov 2020 14:06:36

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Un-reviewed for Safety.	System	24 Nov 2020 12:46:20
DataPoint Un-verified.	System	24 Nov 2020 12:46:20
User entered empty.	System	24 Nov 2020 12:46:20
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 12:46:11
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:19:19
User entered '63104'	Cassandra Zehenny (b) (4)	23 Nov 2020 15:47:56
	(b) (4)	

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 14:49:12
User entered 'US'	System	20 Nov 2020 14:06:52

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 09:39:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	24 Nov 2020 12:46:20
User entered '2'	System	23 Nov 2020 14:49:26
User entered '1'	System	20 Nov 2020 14:06:52

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:39:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '24/Nov/2020 07:46'	System	24 Nov 2020 12:46:20

US3552371

Folder: SAE USA-US089-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:39:31

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.

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	24 Nov 2020 12:46:20