

US3552371 (Prod: Saint Louis University)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:15:53

All time stamps listed in this document are displayed in GMT

US3552371

Form: Participant Creation

Data signed: (b) (4) 21 Feb 2021 18:59:40

Generated On: 10 Jun 2021 08:15:53

Participant ID

US3552371

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

US3552371

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 19:00:00

Generated On: 10 Jun 2021 08:15:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 21 Feb 2021 19:00:00

Generated On: 10 Jun 2021 08:15:53

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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 21 Feb 2021 19:00:00

Generated On: 10 Jun 2021 08:15:53

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 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 21 Feb 2021 19:00:00

Generated On: 10 Jun 2021 08:15:53

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 21 Feb 2021 19:00:00

Generated On: 10 Jun 2021 08:15:53

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 09 Mar 2021 17:01:18

Generated On: 10 Jun 2021 08:15:53

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN OCT 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 09 Mar 2021 17:01:18

Generated On: 10 Jun 2021 08:15:53

Condition	HYPOTHYROID/HASHIMOTOS
Start date (dd MMM yyyy)	UN MAY 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	MAY 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 09 Mar 2021 17:01:18

Generated On: 10 Jun 2021 08:15:53

Condition	GENERALIZED MUSCLE SORENESS
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

US3552371

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 09 Mar 2021 17:01:18

Generated On: 10 Jun 2021 08:15:53

Condition	MITRAL VALVE REPAIR
Start date (dd MMM yyyy)	UN APR 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN APR 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)

Data signed: (b) (4) 09 Mar 2021 17:01:18

Generated On: 10 Jun 2021 08:15:53

Condition	MENOPAUSE
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3552371

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 09 Mar 2021 17:01:18

Generated On: 10 Jun 2021 08:15:53

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 09 Mar 2021 17:01:18

Generated On: 10 Jun 2021 08:15:53

Condition	SULFA ALLERGY
Start date (dd MMM yyyy)	UN UNK 2001
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 09 Mar 2021 17:01:18

Generated On: 10 Jun 2021 08:15:53

Condition	MITRAL REGURGITATION
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN APR 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

US3552371

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 09 Mar 2021 17:01:18

Generated On: 10 Jun 2021 08:15:53

Condition	TEMPOROMANDIPULAR JAW PAIN, LEFT JAW
Start date (dd MMM yyyy)	UN UNK 1982
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1982
Start Year (derived)	1982
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 19:00:00

Generated On: 10 Jun 2021 08:15:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
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
Height (xxx.x)	66 in
Weight (xxx.x)	132 lb
BMI (xxx.x)	21.34990 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 19:00:00

Generated On: 10 Jun 2021 08:15:53

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

Data signed: (b) (4) 21 Feb 2021 19:00:00

Generated On: 10 Jun 2021 08:15:53

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

Data signed: (b) (4) 21 Feb 2021 19:00:00

Generated On: 10 Jun 2021 08:15:53

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

Data signed: (b) (4) 21 Feb 2021 19:00:00

Generated On: 10 Jun 2021 08:15:53

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

Data signed: (b) (4) 21 Feb 2021 19:00:01

Generated On: 10 Jun 2021 08:15:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 21 Feb 2021 19:00:01

Generated On: 10 Jun 2021 08:15:53

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

Data signed: (b) (4) 21 Feb 2021 19:00:01

Generated On: 10 Jun 2021 08:15:53

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 19:00:01

Generated On: 10 Jun 2021 08:15:53

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	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 <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	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)

Data signed: (b) (4) 21 Feb 2021 19:00:01

Generated On: 10 Jun 2021 08:15:53

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	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 <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
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

Data signed: (b) (4) 21 Feb 2021 19:00:01

Generated On: 10 Jun 2021 08:15:53

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

Data signed: (b) (4) 21 Feb 2021 19:00:01

Generated On: 10 Jun 2021 08:15:53

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

Data signed: (b) (4) 21 Feb 2021 19:00:01

Generated On: 10 Jun 2021 08:15:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	08 SEP 2020
Collection time (00:00-23:59)	16:52 (24 HR)
Collection date and time (derived)	08 SEP 2020 16:52

US3552371

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 19:00:00

Generated On: 10 Jun 2021 08:15:53

Collection date (dd MMM yyyy)			08 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	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

Data signed: (b) (4) 21 Feb 2021 19:00:00

Generated On: 10 Jun 2021 08:15:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:15:53

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

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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

No ☒

Yes ☐

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

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

Yes <input type="checkbox"/>	
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: 10 Jun 2021 08:15:53

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 ☒

PRODUCTION RELEASE (v12.003

53 of 2060

EAB) (1725)

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:15:53

Yes <input type="checkbox"/>	
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: 10 Jun 2021 08:15:53

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

55 of 2060

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:15:53

Yes <input type="checkbox"/>	
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: 10 Jun 2021 08:15:53

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 ☒

PRODUCTION RELEASE (v12.003

57 of 2060

EAB) (1725)

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:15:53

Yes <input type="checkbox"/>	
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: 10 Jun 2021 08:15:53

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 ☒

PRODUCTION RELEASE (v12.003

59 of 2060

EAB) (1725)

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:53

Yes <input type="checkbox"/>	
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: 10 Jun 2021 08:15:53

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 ☒

PRODUCTION RELEASE (v12.003

61 of 2060

EAB) (1725)

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:15:53

Yes <input type="checkbox"/>	
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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
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

Data signed: (b) (4) 21 Feb 2021 19:00:00

Generated On: 10 Jun 2021 08:15:53

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

Data signed: (b) (4) 21 Feb 2021 19:00:00

Generated On: 10 Jun 2021 08:15:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552371

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:59:59

Generated On: 10 Jun 2021 08:15:53

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

Data signed: (b) (4) 21 Feb 2021 18:59:59

Generated On: 10 Jun 2021 08:15:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552371

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:59:59

Generated On: 10 Jun 2021 08:15:53

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

Data signed: (b) (4) 21 Feb 2021 18:59:59

Generated On: 10 Jun 2021 08:15:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552371

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 19:00:02

Generated On: 10 Jun 2021 08:15:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 19:00:02

Generated On: 10 Jun 2021 08:15:53

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	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 <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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)

Data signed: (b) (4) 21 Feb 2021 19:00:02

Generated On: 10 Jun 2021 08:15:53

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

US3552371

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 19:00:01

Generated On: 10 Jun 2021 08:15:53

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

Data signed: (b) (4) 21 Feb 2021 19:00:01

Generated On: 10 Jun 2021 08:15:53

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

Data signed: (b) (4) 21 Feb 2021 19:00:01

Generated On: 10 Jun 2021 08:15:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
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

Data signed: (b) (4) 21 Feb 2021 19:00:01

Generated On: 10 Jun 2021 08:15:53

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

Data signed: (b) (4) 21 Feb 2021 19:00:01

Generated On: 10 Jun 2021 08:15:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552371

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:59:59

Generated On: 10 Jun 2021 08:15:53

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

Data signed: (b) (4) 21 Feb 2021 18:59:59

Generated On: 10 Jun 2021 08:15:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552371

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:59:59

Generated On: 10 Jun 2021 08:15:53

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

Data signed: (b) (4) 21 Feb 2021 18:59:59

Generated On: 10 Jun 2021 08:15:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552371

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:59:59

Generated On: 10 Jun 2021 08:15:53

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

Data signed: (b) (4) 21 Feb 2021 18:59:59

Generated On: 10 Jun 2021 08:15:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552371

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 19:00:02

Generated On: 10 Jun 2021 08:15:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3552371

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 19:00:02

Generated On: 10 Jun 2021 08:15:53

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 _____

Height (derived) _____

Weight (derived) _____

US3552371

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 19:00:02

Generated On: 10 Jun 2021 08:15:53

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

Data signed: (b) (4) 21 Feb 2021 19:00:02

Generated On: 10 Jun 2021 08:15:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 NOV 2020
Collection time (00:00-23:59)	10:44 (24 HR)
Collection date and time (derived)	10 NOV 2020 10:44

US3552371

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:00:02

Generated On: 10 Jun 2021 08:15:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552371

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
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: 10 Jun 2021 08:15:53

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	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: 10 Jun 2021 08:15:53

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
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: 10 Jun 2021 08:15:53

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 NOV 2020 12:15:11
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: 10 Jun 2021 08:15:53

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 DEC 2020 12:50:10
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: 10 Jun 2021 08:15:53

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 DEC 2020 09:00:43
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: 10 Jun 2021 08:15:53

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	17 DEC 2020 16:39:57
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: 10 Jun 2021 08:15:53

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 DEC 2020 09:03:33
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: 10 Jun 2021 08:15:53

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 JAN 2021 23:48:17

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: 10 Jun 2021 08:15:53

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 JAN 2021 00:48:36
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: 10 Jun 2021 08:15:53

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

Date and time of submission

14 JAN 2021 12:44:44

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: 10 Jun 2021 08:15:53

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

Date and time of submission

21 JAN 2021 11:45:38

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: 10 Jun 2021 08:15:53

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

Date and time of submission

28 JAN 2021 22:55:28

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: 10 Jun 2021 08:15:53

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	04 FEB 2021 21:52:29
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: 10 Jun 2021 08:15:53

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

Date and time of submission

13 FEB 2021 00:32:40

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: 10 Jun 2021 08:15:53

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

Date and time of submission

18 FEB 2021 00:01:28

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: 10 Jun 2021 08:15:53

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

Date and time of submission

28 FEB 2021 18:02:11

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: 10 Jun 2021 08:15:53

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 MAR 2021 11:47:09
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: 10 Jun 2021 08:15:53

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

Date and time of submission

11 MAR 2021 11:45:53

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: 10 Jun 2021 08:15:53

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 MAR 2021 14:44:18
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: 10 Jun 2021 08:15:53

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

Date and time of submission

25 MAR 2021 11:46:53

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: 10 Jun 2021 08:15:53

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

Date and time of submission

01 APR 2021 11:45:35

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: 10 Jun 2021 08:15:53

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

Date and time of submission

08 APR 2021 09:09:07

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

Date and time of submission

18 APR 2021 00:04:29

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: 10 Jun 2021 08:15:53

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

Date and time of submission

22 APR 2021 09:00:31

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: 10 Jun 2021 08:15:53

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

Date and time of submission

29 APR 2021 11:52:23

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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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

[Patient Cloud Open Date & Time](#)

06 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: 10 Jun 2021 08:15:53

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

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: 10 Jun 2021 08:15:53

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

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: 10 Jun 2021 08:15:53

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

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: 10 Jun 2021 08:15:53

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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

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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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

[Patient Cloud Open Date & Time](#)

01 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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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

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: 10 Jun 2021 08:15:53

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

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: 10 Jun 2021 08:15:53

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

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: 10 Jun 2021 08:15:53

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

[Patient Cloud Open Date & Time](#)

29 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: 10 Jun 2021 08:15:53

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

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: 10 Jun 2021 08:15:53

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

Patient Cloud Open Date & Time	12 AUG 2021 00:01
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Patient Cloud Close Date & Time	16 AUG 2021 23:59
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US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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

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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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

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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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

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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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

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: 10 Jun 2021 08:15:53

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

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: 10 Jun 2021 08:15:53

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

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

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

[Patient Cloud Open Date & Time](#)

30 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: 10 Jun 2021 08:15:53

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

[Patient Cloud Open Date & Time](#)

07 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: 10 Jun 2021 08:15:53

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 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: 10 Jun 2021 08:15:53

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

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: 10 Jun 2021 08:15:53

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

[Patient Cloud Open Date & Time](#)

28 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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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

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: 10 Jun 2021 08:15:53

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°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: 10 Jun 2021 08:15:53

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

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: 10 Jun 2021 08:15:53

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

[Patient Cloud Open Date & Time](#)

18 NOV 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: 10 Jun 2021 08:15:53

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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

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: 10 Jun 2021 08:15:53

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

[Patient Cloud Open Date & Time](#)

09 DEC 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: 10 Jun 2021 08:15:53

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

[Patient Cloud Open Date & Time](#)

16 DEC 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: 10 Jun 2021 08:15:53

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

[Patient Cloud Open Date & Time](#)

23 DEC 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: 10 Jun 2021 08:15:53

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

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: 10 Jun 2021 08:15:53

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

[Patient Cloud Open Date & Time](#)

06 JAN 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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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

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

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

Generated On: 10 Jun 2021 08:15:53

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

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

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

Generated On: 10 Jun 2021 08:15:53

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

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

Generated On: 10 Jun 2021 08:15:53

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

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

Generated On: 10 Jun 2021 08:15:53

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

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

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

Generated On: 10 Jun 2021 08:15:53

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

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

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

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

Generated On: 10 Jun 2021 08:15:53

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

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

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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

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: 10 Jun 2021 08:15:53

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

Generated On: 10 Jun 2021 08:15:53

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

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

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28 MAR 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

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

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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

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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

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: 10 Jun 2021 08:15:53

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

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: 10 Jun 2021 08:15:53

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

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13 JUN 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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

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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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

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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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

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: 10 Jun 2021 08:15:53

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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

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: 10 Jun 2021 08:15:53

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

[Patient Cloud Open Date & Time](#)

21 JUL 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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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

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: 10 Jun 2021 08:15:53

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

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

Date and time of submission

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08 AUG 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

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22 AUG 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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

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: 10 Jun 2021 08:15:53

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

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05 SEP 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

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: 10 Jun 2021 08:15:53

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°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: 10 Jun 2021 08:15:53

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

[Patient Cloud Open Date & Time](#)

29 SEP 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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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

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: 10 Jun 2021 08:15:53

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

[Patient Cloud Open Date & Time](#)

13 OCT 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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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

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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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

[Patient Cloud Open Date & Time](#)

27 OCT 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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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

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: 10 Jun 2021 08:15:53

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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2022 23:59

US3552371

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:15:53

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 18:02:22

US3552371

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:00:00

Generated On: 10 Jun 2021 08:15:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 DEC 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 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:00:00

Generated On: 10 Jun 2021 08:15:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552371

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:59:59

Generated On: 10 Jun 2021 08:15:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 JAN 2021

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 119 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:59:59

Generated On: 10 Jun 2021 08:15:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552371

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:59:59

Generated On: 10 Jun 2021 08:15:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 FEB 2021

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 149 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:59:59

Generated On: 10 Jun 2021 08:15:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552371

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Mar 2021 15:38:48

Generated On: 10 Jun 2021 08:15:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 MAR 2021

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 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 15:38:48

Generated On: 10 Jun 2021 08:15:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552371

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 18:03:23

Generated On: 10 Jun 2021 08:15:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3552371

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 18:03:23

Generated On: 10 Jun 2021 08:15:53

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 _____

Height (derived) _____

Weight (derived) _____

US3552371

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 18:03:23

Generated On: 10 Jun 2021 08:15:53

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 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 18:03:23

Generated On: 10 Jun 2021 08:15:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 APR 2021
Collection time (00:00-23:59)	10:38 (24 HR)
Collection date and time (derived)	13 APR 2021 10:38

US3552371

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 18:03:23

Generated On: 10 Jun 2021 08:15:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552371

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552371

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:53

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3552371

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:15:53

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

US3552371

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:15:53

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	04 FEB 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 23 Mar 2021 15:38:48

Generated On: 10 Jun 2021 08:15:53

Date of updated informed consent (<i>dd MMM yyyy</i>)	04 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	04 FEB 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	1

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 FEB 2021
Time of assessment (00:00-23:59)	09:30 (24 HR)
Vital Signs Date and Time (derived)	04 FEB 2021 09:30
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 FEB 2021
Time of assessment (00:00-23:59)	10:37 (24 HR)
Vital Signs Date and Time (derived)	04 FEB 2021 10:37
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 FEB 2021

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

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 04 FEB 2021

What was the treatment time? (00:00-23:59) 10:07 (24 HR)

Treatment Date and Time (derived) 04 FEB 2021 10:07

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

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 FEB 2021
Collection time (00:00-23:59)	09:15 (24 HR)
Collection date and time (derived)	04 FEB 2021 09:15

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 FEB 2021
Collection time (00:00 - 23:59)	09:19
Collection Date and Time (derived)	04 FEB 2021 09:19

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552371

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 19:00:00

Generated On: 10 Jun 2021 08:15:53

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 FEB 2021

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 OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 19:00:00

Generated On: 10 Jun 2021 08:15:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

OLD29 Placebo Flag

1

US3552371

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 17:01:17

Generated On: 10 Jun 2021 08:15:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3552371

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Mar 2021 17:01:17

Generated On: 10 Jun 2021 08:15:53

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 _____

Height (derived) _____

Weight (derived) _____

US3552371

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 17:01:17

Generated On: 10 Jun 2021 08:15:53

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: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 17:01:17

Generated On: 10 Jun 2021 08:15:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 MAR 2021
Collection time (00:00-23:59)	10:42 (24 HR)
Collection date and time (derived)	3 MAR 2021 10:42

US3552371

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

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)

Data signed: (b) (4) 21 Feb 2021 18:59:40

Generated On: 10 Jun 2021 08:15:53

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

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 21 Feb 2021 18:59:40

Generated On: 10 Jun 2021 08:15:53

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>

Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>

Action taken with investigational product	None <input checked="" type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input type="radio"/>

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input checked="" type="radio"/>
	Recovered/Resolved with Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input type="radio"/>

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative	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)	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 21 Feb 2021 18:59:40

Generated On: 10 Jun 2021 08:15:53

AEID	
Adverse event	ELEVATED LIVER ENZYMES
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 21 Feb 2021 18:59:40

Generated On: 10 Jun 2021 08:15:53

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 21 Feb 2021 18:59:40

Generated On: 10 Jun 2021 08:15:53

AEID	USA-US089-2020-MRNA-1273-P30 1000012
Adverse event	RIGHT KIDNEY RENAL CELL CARCINOMA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	08 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	13 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	12 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	13 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 21 Feb 2021 18:59:40

Generated On: 10 Jun 2021 08:15:53

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

US3552371

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 21 Feb 2021 18:59:40

Generated On: 10 Jun 2021 08:15:53

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)

Data signed: (b) (4) 21 Feb 2021 18:59:40

Generated On: 10 Jun 2021 08:15:53

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 21 Feb 2021 18:59:40

Generated On: 10 Jun 2021 08:15:53

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

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

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)

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 21 Feb 2021 18:59:41

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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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAY 1995	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 21 Feb 2021 18:59:41

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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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 21 Feb 2021 18:59:41

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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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA 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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

Name of Medication PERCOCET
[OXYCODONE-ACETAMINOPHE
N]

Prophylaxis Yes ☐
No ☒

Indication PARTIAL NEPHRECTOMY

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

Name of Medication CRYSTALLOID FLUIDS
[INGREDIENTS UNKNOWN]

Prophylaxis Yes ☐
No ☒

Indication PARTIAL NEPHRECTOMY

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

CONTINUOUS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

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

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

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

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

Name of Medication AMOXICILLIN

Prophylaxis Yes ☒
No ☐

Indication DENTAL PROCEDURE
PROPHYLAXIS

Dose per administration 2000

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3552371

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3552371

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Feb 2021 03:30:18

Generated On: 10 Jun 2021 08:15:53

Procedure/Surgery date (dd MMM yyyy)	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	
11 JAN 2021	DENTAL PROCEDURE	Other	ROUTINE DENTAL CLEANING

US3552371

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 21 Feb 2021 18:59:41

Generated On: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

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

Data signed: (b) (4) 21 Feb 2021 18:59:59

Generated On: 10 Jun 2021 08:15:53

SAEID	USA-US089-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	4

US3552371

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

Form: Safety Report Form (1)

Data signed: (b) (4) 21 Feb 2021 18:59:59

Generated On: 10 Jun 2021 08:15:53

SAEID	USA-US089-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	4
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)

Data signed: (b) (4) 21 Feb 2021 18:59:59

Generated On: 10 Jun 2021 08:15:53

SAEID	USA-US089-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	4
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)

Data signed: (b) (4) 21 Feb 2021 18:59:59

Generated On: 10 Jun 2021 08:15:53

SAEID	USA-US089-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	4
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

US3552371

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

Form: Safety Report Form (4)

Data signed: (b) (4) 21 Feb 2021 18:59:59

Generated On: 10 Jun 2021 08:15:53

SAEID	USA-US089-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	4
Date of submission (Pre-filled from custom function)	20/JAN/2021 22:29
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: 10 Jun 2021 08:15:53

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:18:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered 'US3552371'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 21:44:28

US3552371

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:15:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered 'SCRN'	System	09 Sep 2020 20:19:12

US3552371

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:53

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:30:37
User entered (b) (6) 1964'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Sep 2020 21:44:30

US3552371

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:53

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:30:37
User entered '56'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:20:06

US3552371

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:53

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered 'YEARS'	System	09 Sep 2020 20:20:06

US3552371

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:53

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered '56'	System	08 Sep 2020 21:57:22

US3552371

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:53

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:30:37
User entered 'Female (F)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:20:06

US3552371

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:53

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:30:37
User entered 'l'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:20:06

US3552371

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:53

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:30:37
User entered '0'	Stanley Dublin (b) (4)	09 Sep 2020 20:20:06

US3552371

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:53

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:30:37
User entered '0'	Stanley Doublin (b) (4)	09 Sep 2020 20:20:06
	(b) (4)	

US3552371

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:53

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	15 Oct 2020 19:30:37
User entered '0'	Stanley Dublin (b) (4)	09 Sep 2020 20:20:06
	(b) (4)	

US3552371

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:15:53

Date of Informed Consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	10 Nov 2020 20:44:28
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 20:44:28
	Mikayla Frye (b) (4)	10 Nov 2020 17:35:12
	(b) (4)	10 Nov 2020 17:35:12
User entered '08 Sep 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	10 Nov 2020 17:35:12
	(b) (4)	10 Nov 2020 17:35:12
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:30:49
	(b) (4)	15 Oct 2020 19:30:49
User entered '8 Sep 2020'	Cassandra Zehenny (b) (4)	08 Sep 2020 21:57:22
	(b) (4)	08 Sep 2020 21:57:22

US3552371

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered 'Sep 2020'	System	08 Sep 2020 21:57:22

US3552371

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered '2020'	System	08 Sep 2020 21:57:22

US3552371

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:15:53

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:30:49
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	08 Sep 2020 21:57:22

US3552371

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:15:53

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:30:49
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	08 Sep 2020 21:57:22

US3552371

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:15:53

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	15 Oct 2020 19:30:49
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 19:30:49
	RWS_ENDPOINT	08 Sep 2020 21:44:29
	ENDPOINT (b) (4)	

US3552371

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:15:53

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered 'l'	System	08 Sep 2020 21:57:28

US3552371

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:31:06
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	08 Sep 2020 21:57:28

US3552371

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:15:53

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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 Dublin (b) (4) (b) (4)	09 Sep 2020 20:22:24

US3552371

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered '0'	Stanley Doublin (b) (4)	09 Sep 2020 20:22:24

US3552371

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:15:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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).	(b) (4), (b) (6)	09 Sep 2020 20:22:33
User entered 'Yes (Y)' reason for change: Data Entry Error	System	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).	Stanley Dublin (b) (4)	09 Sep 2020 20:22:24
User entered 'No (N)'	(b) (4)	09 Sep 2020 20:22:24

US3552371

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered empty.	Stanley Dublin (b) (4) (b) (4)	09 Sep 2020 20:22:24

US3552371

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:15:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered 'Oct 2018'	System	09 Sep 2020 20:22:24

US3552371

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:15:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered '2018'	System	09 Sep 2020 20:22:24

US3552371

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered empty.	System	09 Sep 2020 20:22:24

US3552371

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered empty.	System	09 Sep 2020 20:22:24

US3552371

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:15:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered 'un May 1995'	Stanley Dublin (b) (4) (b) (4)	09 Sep 2020 20:23:20

US3552371

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:15:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	15 Oct 2020 19:32:45
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 19:32:45
	Stanley Doublin (b) (4)	09 Sep 2020 20:23:20
	(b) (4)	

US3552371

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered 'May 1995'	System	09 Sep 2020 20:23:20

US3552371

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:15:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered '1995'	System	09 Sep 2020 20:23:20

US3552371

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered empty.	System	09 Sep 2020 20:23:20

US3552371

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered empty.	System	09 Sep 2020 20:23:20

US3552371

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:15:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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.	(b) (4), (b) (6)	27 Oct 2020 09:41:52
' (Site from DM).		
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)	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)	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.	(b) (4), (b) (6)	26 Oct 2020 15:29:34
' answered with 'Resolved' (Site from DM).		
DataPoint Un-verified.		26 Oct 2020 15:29:25
Coding entries removed.		26 Oct 2020 15:29:25
User entered 'Generalized MUSCLE SORENESS' reason for change: Data Entry Error		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.		23 Oct 2020 14:48:33
' (Site from DM).		
DataPoint Verified.		15 Oct 2020 19:32:45

US3552371

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:15:53

[Condition](#)

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

US3552371

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered empty.	Stanley Dublin (b) (4)	09 Sep 2020 20:23:39

US3552371

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:15:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered 'Jan 2012'	System	09 Sep 2020 20:23:39

US3552371

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered '2012'	System	09 Sep 2020 20:23:39

US3552371

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered empty.	System	09 Sep 2020 20:23:39

US3552371

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered empty.	System	09 Sep 2020 20:23:39

US3552371

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:15:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	(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).		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 Dublin (b) (4)	09 Sep 2020 20:24:03

US3552371

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered 'un Apr 1995'	Stanley Dublin (b) (4) (b) (4)	09 Sep 2020 20:24:03

US3552371

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:15:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered 'Apr 1995'	System	09 Sep 2020 20:24:03

US3552371

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:15:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered '1995'	System	09 Sep 2020 20:24:03

US3552371

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered 'Apr 1995'	System	09 Sep 2020 20:24:03

US3552371

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered '1995'	System	09 Sep 2020 20:24:03

US3552371

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:15:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered '0'	Stanley Dublin (b) (4) (b) (4)	09 Sep 2020 20:27:23

US3552371

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:15:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	15 Oct 2020 19:32:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 19:32:45
	Stanley Doublin (b) (4)	09 Sep 2020 20:27:23
	(b) (4)	

US3552371

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered empty.	Stanley Dublin (b) (4) (b) (4)	09 Sep 2020 20:27:23

US3552371

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:15:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered 'Jan 2018'	System	09 Sep 2020 20:27:23

US3552371

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:15:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered '2018'	System	09 Sep 2020 20:27:23

US3552371

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered empty.	System	09 Sep 2020 20:27:23

US3552371

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered empty.	System	09 Sep 2020 20:27:23

US3552371

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:15:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	
	(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)	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)	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)	09 Sep 2020 20:28:00
	(b) (4)	

US3552371

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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

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Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:15:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered empty.	Stanley Doublin (b) (4)	09 Sep 2020 20:28:00

US3552371

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:15:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered 'Jan 2012'	System	09 Sep 2020 20:28:00

US3552371

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered '2012'	System	09 Sep 2020 20:28:00

US3552371

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered empty.	System	09 Sep 2020 20:28:00

US3552371

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered empty.	System	09 Sep 2020 20:28:00

US3552371

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:15:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:32:45
User coded data point as SOC: Immune system disorders, HLG: 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)	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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered empty.	Stanley Dublin (b) (4) (b) (4)	09 Sep 2020 20:28:12

US3552371

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:15:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered 'Jan 2001'	System	09 Sep 2020 20:28:12

US3552371

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:15:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered '2001'	System	09 Sep 2020 20:28:12

US3552371

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered empty.	System	09 Sep 2020 20:28:12

US3552371

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered empty.	System	09 Sep 2020 20:28:12

US3552371

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:15:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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) (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) (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) (b) (4)	06 Oct 2020 13:55:05

US3552371

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered 'un UNK 1995'	Joan Siegner (b) (4) (b) (4)	06 Oct 2020 13:55:05

US3552371

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:15:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:45
User entered '0'	Joan Siegner (b) (4) (b) (4)	06 Oct 2020 13:55:05

US3552371

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered 'Jan 1995'	System	06 Oct 2020 13:55:05

US3552371

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered '1995'	System	06 Oct 2020 13:55:05

US3552371

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered 'Apr 1995'	System	06 Oct 2020 13:55:05

US3552371

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered '1995'	System	06 Oct 2020 13:55:05

US3552371

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:15:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
DataPoint Verified.	(b) (4)	18 Mar 2021 17:01:02
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Bone related signs and symptoms, PT: Pain in jaw, LLT: Jaw pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:38:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:38:01
User signature succeeded.	sharon frey (b) (4) (b) (4)	09 Mar 2021 17:01:18
Data point term sent to Coder	System	03 Mar 2021 19:56:12
User entered 'Temporomandipular jaw pain, left jaw'	Heather Douds (b) (4) (b) (4)	03 Mar 2021 19:55:39

US3552371

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
DataPoint Verified.		18 Mar 2021 17:01:02
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:01:18
User entered 'un UNK 1982'	(b) (4) Heather Douds (b) (4) (b) (4)	03 Mar 2021 19:55:39

US3552371

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:15:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
DataPoint Verified.		18 Mar 2021 17:01:02
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:01:18
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	03 Mar 2021 19:55:39

US3552371

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:15:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
DataPoint Verified.		18 Mar 2021 17:01:02
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:01:18
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	03 Mar 2021 19:55:39

US3552371

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
DataPoint Verified.		18 Mar 2021 17:01:02
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:01:18
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	03 Mar 2021 19:55:39

US3552371

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:15:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
DataPoint Verified.		18 Mar 2021 17:01:02
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:01:18
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	03 Mar 2021 19:55:39

US3552371

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered 'Jan 1982'	System	03 Mar 2021 19:55:39

US3552371

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:15:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered '1982'	System	03 Mar 2021 19:55:39

US3552371

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered empty.	System	03 Mar 2021 19:55:39

US3552371

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered empty.	System	03 Mar 2021 19:55:39

US3552371

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 20:47:35
DataPoint Un-verified.	Mikayla Frye (b) (4)	10 Nov 2020 17:35:26
	(b) (4)	
User entered '08 Sep 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	10 Nov 2020 17:35:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:53
User entered '8 Sep 2020'	Stanley Dublin (b) (4)	09 Sep 2020 20:28:44
	(b) (4)	

US3552371

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	15 Oct 2020 19:32:53
User entered '66' in	(b) (4), (b) (6)	15 Oct 2020 19:32:53
DataPoint set to visible.	Stanley Doublin (b) (4)	09 Sep 2020 20:28:44
	(b) (4)	08 Sep 2020 21:57:28
	System	

US3552371

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	15 Oct 2020 19:32:53
User entered '132' lb	(b) (4), (b) (6)	15 Oct 2020 19:32:53
	Stanley Doublin (b) (4)	09 Sep 2020 20:28:44
DataPoint set to visible.	(b) (4)	08 Sep 2020 21:57:28
	System	08 Sep 2020 21:57:28

US3552371

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
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: 10 Jun 2021 08:15:53

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
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: 10 Jun 2021 08:15:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:32:53
User entered empty.	Stanley Dublin (b) (4) (b) (4)	09 Sep 2020 20:28:44

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered 'bpm'	System	09 Sep 2020 20:28:44

US3552371

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered 'breaths/min'	System	09 Sep 2020 20:28:44

US3552371

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered 'mmHg'	System	09 Sep 2020 20:28:44

US3552371

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User entered 'mmHg'	System	09 Sep 2020 20:28:44

US3552371

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38

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Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	10 Nov 2020 20:47:43
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 20:47:43
	Mikayla Frye (b) (4)	10 Nov 2020 17:35:30
	(b) (4)	10 Nov 2020 17:35:30
User entered '08 Sep 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	10 Nov 2020 17:35:30
	(b) (4)	10 Nov 2020 17:35:30
DataPoint Verified.	(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)	09 Sep 2020 20:28:53

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:15:53

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 20:47:48
DataPoint Un-verified.	Mikayla Frye (b) (4)	10 Nov 2020 17:35:36
	(b) (4)	
User entered '08 Sep 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	10 Nov 2020 17:35:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:06
User entered '8 Sep 2020'	Stanley Dublin (b) (4)	09 Sep 2020 20:29:14
	(b) (4)	

US3552371

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	15 Oct 2020 19:34:06
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Stanley Dublin (b) (4)	09 Sep 2020 20:29:14

US3552371

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:15:53

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:20
User entered 'No (N)'	Stanley Doublin (b) (4)	09 Sep 2020 20:31:34

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Folder: Screening

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	15 Oct 2020 19:34:20
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 19:34:20
	Stanley Doublin (b) (4)	09 Sep 2020 20:31:34
	(b) (4)	

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:20
User entered 'No (N)'	Stanley Doublin (b) (4)	09 Sep 2020 20:31:34

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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 Dublin (b) (4)	09 Sep 2020 20:31:34

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Sep 2020 20:31:34

US3552371

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:53

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	15 Oct 2020 19:34:20
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 19:34:20
	Stanley Doublin (b) (4)	09 Sep 2020 20:31:34
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:20
User entered '0'	Stanley Dublin (b) (4) (b) (4)	09 Sep 2020 20:31:34

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	15 Oct 2020 19:34:20
User entered 'l'	(b) (4), (b) (6)	15 Oct 2020 19:34:20
	Stanley Doublin (b) (4)	09 Sep 2020 20:31:34
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:20
User entered '0'	Stanley Dublin (b) (4) (b) (4)	09 Sep 2020 20:31:34

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:53

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	09 Sep 2020 20:31:34

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:53

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:15:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	15 Oct 2020 19:34:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 19:34:29
	Stanley Doublin (b) (4)	09 Sep 2020 20:31:53
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:47:59
DataPoint Un-verified.	Mikayla Frye (b) (4) (b) (4)	10 Nov 2020 17:35:44
User entered '08 Sep 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4) (b) (4)	10 Nov 2020 17:35:44
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:29
User entered '8 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	09 Sep 2020 20:31:53

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:15:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered 'VISIT1'	System	09 Sep 2020 20:31:53

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	15 Oct 2020 19:34:38
User entered '08 SEP 2020'	(b) (4), (b) (6)	15 Oct 2020 19:34:38
	RWS_ENDPOINT	08 Sep 2020 21:59:15
	ENDPOINT (b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:15:53

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:34:38
User entered '112401'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Sep 2020 21:59:15

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	15 Oct 2020 19:34:38
User entered '>=18 and <65 years and not at risk (1)'	(b) (4), (b) (6)	
	RWS_ENDPOINT	15 Oct 2020 19:34:38
	ENDPOINT (b) (4)	08 Sep 2020 21:59:15

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	15 Oct 2020 19:34:38
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 19:34:38
	Stanley Doublin (b) (4)	09 Sep 2020 20:32:03
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:15:53

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:15:53

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	15 Oct 2020 19:34:38
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 19:34:38
	Stanley Doublin (b) (4)	21 Sep 2020 18:02:44
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:44:23
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:44:22

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:15:53

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:36
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	09 Sep 2020 20:32:46

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:15:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:36
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	09 Sep 2020 20:32:46

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:15:53

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:15:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:36
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	09 Sep 2020 20:32:46

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	09 Sep 2020 20:32:46

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:53

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	10 Nov 2020 20:48:11
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 20:48:11
	Mikayla Frye (b) (4)	10 Nov 2020 17:35:53
	(b) (4)	10 Nov 2020 17:35:53
User entered '08 Sep 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	10 Nov 2020 17:35:53
	(b) (4)	10 Nov 2020 17:35:53
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:36
	(b) (4), (b) (6)	15 Oct 2020 19:35:36
User entered '8 Sep 2020'	Stanley Dublin (b) (4)	09 Sep 2020 20:32:46
	(b) (4)	09 Sep 2020 20:32:46

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	15 Oct 2020 19:35:36
User entered '16:34'	(b) (4), (b) (6)	15 Oct 2020 19:35:36
	Stanley Doublin (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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:36
User entered '90'	Stanley Dublin (b) (4) (b) (4)	09 Sep 2020 20:32:46

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered 'bpm'	System	09 Sep 2020 20:32:46

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered 'breaths/min'	System	09 Sep 2020 20:32:46

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:36
User entered '117'	Stanley Dublin (b) (4) (b) (4)	09 Sep 2020 20:32:46

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered 'mmHg'	System	09 Sep 2020 20:32:46

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered 'mmHg'	System	09 Sep 2020 20:32:46

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:15:53

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	15 Oct 2020 19:35:36
User entered missing code ND - Not Done.	(b) (4), (b) (6)	15 Oct 2020 19:35:36
	Stanley Doublin (b) (4)	09 Sep 2020 20:32:46
	(b) (4)	

US3552371

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User accepted default value 'Post-Dose (POSTDOSE)'	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: 10 Jun 2021 08:15:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	10 Nov 2020 20:48:16
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 20:48:16
	Mikayla Frye (b) (4)	10 Nov 2020 17:35:53
	(b) (4)	10 Nov 2020 17:35:53
User entered '08 Sep 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	10 Nov 2020 17:35:53
	(b) (4)	10 Nov 2020 17:35:53
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:36
	(b) (4), (b) (6)	15 Oct 2020 19:35:36
User entered '8 Sep 2020'	Stanley Dublin (b) (4)	09 Sep 2020 20:33:30
	(b) (4)	09 Sep 2020 20:33:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
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: 10 Jun 2021 08:15:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:36
User entered empty.	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: 10 Jun 2021 08:15:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered 'bpm'	System	09 Sep 2020 20:33:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered 'breaths/min'	System	09 Sep 2020 20:33:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered 'mmHg'	System	09 Sep 2020 20:33:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered 'mmHg'	System	09 Sep 2020 20:33:30

US3552371

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	10 Nov 2020 20:48:25
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 20:48:25
	Mikayla Frye (b) (4)	10 Nov 2020 17:35:58
	(b) (4)	
User entered '08 Sep 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	10 Nov 2020 17:35:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:46
User entered '8 Sep 2020'	Stanley Dublin (b) (4)	09 Sep 2020 20:34:41
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:15:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 22:36:24

US3552371

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	10 Nov 2020 20:48:31
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 20:48:31
	Mikayla Frye (b) (4)	10 Nov 2020 17:36:04
	(b) (4)	10 Nov 2020 17:36:04
User entered '08 Sep 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	10 Nov 2020 17:36:04
	(b) (4)	10 Nov 2020 17:36:04
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:57
	(b) (4)	15 Oct 2020 19:35:57
User entered '8 Sep 2020'	Cassandra Zehenny (b) (4)	08 Sep 2020 22:36:24
	(b) (4)	08 Sep 2020 22:36:24

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:35:57
User entered 'Left Arm (LEFT ARM)'	Cassandra Zehenny (b) (4) (b) (4)	08 Sep 2020 22:36:24

US3552371

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
DataPoint Verified.		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: 10 Jun 2021 08:15:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 22:36:24

US3552371

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	10 Nov 2020 20:48:38
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 20:48:38
	Mikayla Frye (b) (4)	10 Nov 2020 17:36:09
	(b) (4)	
User entered '08 Sep 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	10 Nov 2020 17:36:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:36:06
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: 10 Jun 2021 08:15:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
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: 10 Jun 2021 08:15:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	10 Nov 2020 20:48:46
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 20:48:46
	Mikayla Frye (b) (4)	10 Nov 2020 17:36:14
	(b) (4)	10 Nov 2020 17:36:14
User entered '08 Sep 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	10 Nov 2020 17:36:14
	(b) (4)	10 Nov 2020 17:36:14
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:36:14
User entered '8 Sep 2020'	Stanley Dublin (b) (4)	09 Sep 2020 20:35:07
	(b) (4)	09 Sep 2020 20:35:07

US3552371

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:15:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	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: 10 Jun 2021 08:15:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:15:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
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: 10 Jun 2021 08:15:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Dublin (b) (4) (b) (4)	09 Sep 2020 20:35:07

US3552371

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:15:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered empty.	System	09 Sep 2020 20:35:07

US3552371

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered 'I'	System	16 Sep 2020 14:26:00

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:15:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'Yes (Y)'	System	08 Sep 2020 22:51:49
	System	08 Sep 2020 22:51:49

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:15:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered '98.9'	System	08 Sep 2020 22:51:49
	System	08 Sep 2020 22:51:49

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'No (N)'	System	08 Sep 2020 22:51:49
	System	08 Sep 2020 22:51:49

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:15:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered '08 Sep 2020 17:51'	System	08 Sep 2020 22:51:49
	System	08 Sep 2020 22:51:49

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:15:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered '97.1'	System	09 Sep 2020 14:22:33
	System	09 Sep 2020 14:22:33

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'Yes (Y)'	System	09 Sep 2020 23:23:12
	System	09 Sep 2020 23:23:12

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:15:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 'fecc07b-12a9-42a5-9c37-3e3a14cbb01e' User entered '98.8'	System	09 Sep 2020 23:23:12
	System	09 Sep 2020 23:23:12

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered '09 Sep 2020 18:23'	System	09 Sep 2020 23:23:12
	System	09 Sep 2020 23:23:12

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:15:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'Yes (Y)'	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: 10 Jun 2021 08:15:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered '98.8'	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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'No (N)'	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: 10 Jun 2021 08:15:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered '98.6'	System	11 Sep 2020 20:45:24
	System	11 Sep 2020 20:45:24

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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-ac5563ba69b3' User entered 'Yes (Y)'	System	12 Sep 2020 19:25:53
	System	12 Sep 2020 19:25:53

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:15:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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-ac5563ba69b3' User entered '98.3'	System	12 Sep 2020 19:25:53
	System	12 Sep 2020 19:25:53

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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-ac5563ba69b3'	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: 10 Jun 2021 08:15:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'Yes (Y)'	System	13 Sep 2020 18:29:11
	System	13 Sep 2020 18:29:11

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:15:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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
	System	13 Sep 2020 18:29:11

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'No (N)'	System	13 Sep 2020 18:29:11
	System	13 Sep 2020 18:29:11

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:15:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered '13 Sep 2020 14:28'	System	13 Sep 2020 18:29:11
	System	13 Sep 2020 18:29:11

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:15:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'Yes (Y)'	System	15 Sep 2020 02:33:41
	System	15 Sep 2020 02:33:41

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:15:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered '98.1'	System	15 Sep 2020 02:33:41
	System	15 Sep 2020 02:33:41

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'No (N)'	System	15 Sep 2020 02:33:41
	System	15 Sep 2020 02:33:41

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:15:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered '14 Sep 2020 21:33'	System	15 Sep 2020 02:33:41
	System	15 Sep 2020 02:33:41

US3552371

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:15:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered '08 Sep 2020 17:52'	System	08 Sep 2020 22:52:35
	System	08 Sep 2020 22:52:35

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:15:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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
	System	09 Sep 2020 14:23:13

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:15:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (1)'	System	10 Sep 2020 18:20:17
	System	10 Sep 2020 18:20:17

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:15:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'No (N)'	System	10 Sep 2020 18:20:17
	System	10 Sep 2020 18:20:17

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'No (N)'	System	10 Sep 2020 18:20:17
	System	10 Sep 2020 18:20:17

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:15:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (1)'	System	10 Sep 2020 18:20:17
	System	10 Sep 2020 18:20:17

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:15:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered '10 Sep 2020 13:20'	System	10 Sep 2020 18:20:17
	System	10 Sep 2020 18:20:17

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:15:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'No (N)'	System	11 Sep 2020 20:44:59
	System	11 Sep 2020 20:44:59

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered '11 Sep 2020 16:44'	System	11 Sep 2020 20:44:59
	System	11 Sep 2020 20:44:59

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:15:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'No (N)'	System	12 Sep 2020 19:25:28
	System	12 Sep 2020 19:25:28

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'No (N)'	System	12 Sep 2020 19:25:28
	System	12 Sep 2020 19:25:28

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:15:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (1)'	System	12 Sep 2020 19:25:28
	System	12 Sep 2020 19:25:28

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:15:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered '12 Sep 2020 15:25'	System	12 Sep 2020 19:25:28
	System	12 Sep 2020 19:25:28

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:15:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'No (N)'	System	15 Sep 2020 02:33:53
	System	15 Sep 2020 02:33:53

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'No (N)'	System	15 Sep 2020 02:33:53
	System	15 Sep 2020 02:33:53

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:15:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (1)'	System	15 Sep 2020 02:33:53
	System	15 Sep 2020 02:33:53

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:15:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered '14 Sep 2020 21:33'	System	15 Sep 2020 02:33:53
	System	15 Sep 2020 02:33:53

US3552371

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:15:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (0)'	System	08 Sep 2020 22:53:17
	System	08 Sep 2020 22:53:17

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:15:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (0)'	System	08 Sep 2020 22:53:17
	System	08 Sep 2020 22:53:17

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:15:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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
	System	08 Sep 2020 22:53:17

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:15:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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
	System	08 Sep 2020 22:53:17

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:15:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (0)'	System	08 Sep 2020 22:53:17
	System	08 Sep 2020 22:53:17

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:15:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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
	System	08 Sep 2020 22:53:17

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'No (N)'	System	08 Sep 2020 22:53:17
	System	08 Sep 2020 22:53:17

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:15:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered '08 Sep 2020 17:53'	System	08 Sep 2020 22:53:17
	System	08 Sep 2020 22:53:17

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:15:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (0)'	System	09 Sep 2020 14:23:47
	System	09 Sep 2020 14:23:47

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:15:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (0)'	System	09 Sep 2020 14:23:47
	System	09 Sep 2020 14:23:47

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:15:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (0)'	System	09 Sep 2020 14:23:47
	System	09 Sep 2020 14:23:47

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:15:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered '09 Sep 2020 09:23'	System	09 Sep 2020 14:23:47
	System	09 Sep 2020 14:23:47

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:15:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (0)'	System	09 Sep 2020 23:24:41
	System	09 Sep 2020 23:24:41

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:15:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (0)'	System	09 Sep 2020 23:24:41
	System	09 Sep 2020 23:24:41

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:15:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (0)'	System	09 Sep 2020 23:24:41
	System	09 Sep 2020 23:24:41

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:15:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (0)'	System	09 Sep 2020 23:24:41
	System	09 Sep 2020 23:24:41

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:15:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (0)'	System	09 Sep 2020 23:24:41
	System	09 Sep 2020 23:24:41

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:15:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (0)'	System	09 Sep 2020 23:24:41
	System	09 Sep 2020 23:24:41

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'No (N)'	System	09 Sep 2020 23:24:41
	System	09 Sep 2020 23:24:41

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:15:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered '09 Sep 2020 18:24'	System	09 Sep 2020 23:24:41
	System	09 Sep 2020 23:24:41

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:15:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (0)'	System	10 Sep 2020 18:20:55
	System	10 Sep 2020 18:20:55

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:15:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (0)'	System	10 Sep 2020 18:20:55
	System	10 Sep 2020 18:20:55

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:15:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (0)'	System	10 Sep 2020 18:20:55
	System	10 Sep 2020 18:20:55

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:15:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (0)'	System	10 Sep 2020 18:20:55
	System	10 Sep 2020 18:20:55

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:15:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (0)'	System	10 Sep 2020 18:20:55
	System	10 Sep 2020 18:20:55

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered '10 Sep 2020 13:20'	System	10 Sep 2020 18:20:55
	System	10 Sep 2020 18:20:55

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:15:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (0)'	System	11 Sep 2020 20:44:40
	System	11 Sep 2020 20:44:40

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:15:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (0)'	System	11 Sep 2020 20:44:40
	System	11 Sep 2020 20:44:40

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:15:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (0)'	System	11 Sep 2020 20:44:40
	System	11 Sep 2020 20:44:40

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:15:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (0)'	System	11 Sep 2020 20:44:40
	System	11 Sep 2020 20:44:40

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:15:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (0)'	System	11 Sep 2020 20:44:40
	System	11 Sep 2020 20:44:40

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'No (N)'	System	11 Sep 2020 20:44:40
	System	11 Sep 2020 20:44:40

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:15:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered '11 Sep 2020 16:44'	System	11 Sep 2020 20:44:40
	System	11 Sep 2020 20:44:40

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:15:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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-ac22-b665d7a312db' User entered 'None (0)'	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: 10 Jun 2021 08:15:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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-ac22-b665d7a312db' User entered 'None (0)'	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: 10 Jun 2021 08:15:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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-ac22-b665d7a312db' User entered 'None (0)'	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: 10 Jun 2021 08:15:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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-ac22-b665d7a312db' User entered 'None (0)'	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: 10 Jun 2021 08:15:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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-ac22-b665d7a312db' User entered 'None (0)'	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: 10 Jun 2021 08:15:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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-ac22-b665d7a312db' User entered 'None (0)'	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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'No (N)'	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: 10 Jun 2021 08:15:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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-ac22-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: 10 Jun 2021 08:15:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (0)'	System	13 Sep 2020 18:29:25
	System	13 Sep 2020 18:29:25

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (0)'	System	13 Sep 2020 18:29:25
	System	13 Sep 2020 18:29:25

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (0)'	System	13 Sep 2020 18:29:25
	System	13 Sep 2020 18:29:25

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (0)'	System	13 Sep 2020 18:29:25
	System	13 Sep 2020 18:29:25

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (0)'	System	13 Sep 2020 18:29:25
	System	13 Sep 2020 18:29:25

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (0)'	System	13 Sep 2020 18:29:25
	System	13 Sep 2020 18:29:25

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'No (N)'	System	13 Sep 2020 18:29:25
	System	13 Sep 2020 18:29:25

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered '13 Sep 2020 14:29'	System	13 Sep 2020 18:29:25
	System	13 Sep 2020 18:29:25

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (0)'	System	15 Sep 2020 02:34:23
	System	15 Sep 2020 02:34:23

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:15:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (0)'	System	15 Sep 2020 02:34:23
	System	15 Sep 2020 02:34:23

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:15:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (0)'	System	15 Sep 2020 02:34:23
	System	15 Sep 2020 02:34:23

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:15:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (0)'	System	15 Sep 2020 02:34:23
	System	15 Sep 2020 02:34:23

US3552371

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (0)'	System	15 Sep 2020 21:17:26
	System	15 Sep 2020 21:17:26

US3552371

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:15:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered '15 Sep 2020 16:17'	System	15 Sep 2020 21:17:26
	System	15 Sep 2020 21:17:26

US3552371

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:15:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered 'None (0)'	System	15 Sep 2020 21:17:33
	System	15 Sep 2020 21:17:33

US3552371

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:15:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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' User entered '15 Sep 2020 16:17'	System	15 Sep 2020 21:17:33
	System	15 Sep 2020 21:17:33

US3552371

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:15:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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-8d67-7a16cf3f81d2'	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: 10 Jun 2021 08:15:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:37:15
User entered '15 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	16 Sep 2020 14:26:10

US3552371

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User entered 'l'	System	23 Sep 2020 15:08:27

US3552371

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:40:03
User entered '22 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 15:08:36

US3552371

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	15 Oct 2020 19:40:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	15 Oct 2020 19:40:03
	Stanley Dublin (b) (4)	23 Sep 2020 15:08:36
	(b) (4)	

US3552371

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User entered 'l'	System	29 Sep 2020 16:55:11

US3552371

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	15 Oct 2020 19:41:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	15 Oct 2020 19:41:55
	Stanley Doublin (b) (4)	29 Sep 2020 16:55:19
	(b) (4)	

US3552371

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User entered 'l'	System	13 Oct 2020 16:56:15

US3552371

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered 'VISIT2'	System	13 Oct 2020 16:56:25

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User accepted default value 'Pre-Dose (PREDOSE)'	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: 10 Jun 2021 08:15:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	15 Oct 2020 19:43:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 19:43:04
	Stanley Doublin (b) (4)	13 Oct 2020 16:57:25
	(b) (4)	

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
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: 10 Jun 2021 08:15:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:04
User entered empty.	Stanley Dublin (b) (4) (b) (4)	13 Oct 2020 16:57:25

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered 'bpm'	System	13 Oct 2020 16:57:25

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:04
User entered '16'	Stanley Dublin (b) (4) (b) (4)	13 Oct 2020 16:57:25

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
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: 10 Jun 2021 08:15:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered 'mmHg'	System	13 Oct 2020 16:57:25

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered 'mmHg'	System	13 Oct 2020 16:57:25

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User accepted default value 'Post-Dose (POSTDOSE)'	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: 10 Jun 2021 08:15:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:04
User entered empty.	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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	15 Oct 2020 19:43:04
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 19:43:04
	Stanley Dublin (b) (4)	13 Oct 2020 16:58:37
	(b) (4)	

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered empty.	System	13 Oct 2020 16:58:37

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:04
User entered empty.	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: 10 Jun 2021 08:15:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:04
User entered empty.	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: 10 Jun 2021 08:15:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:04
User entered empty.	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: 10 Jun 2021 08:15:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:04
User entered empty.	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: 10 Jun 2021 08:15:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered empty.	System	13 Oct 2020 16:58:37

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:04
User entered empty.	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: 10 Jun 2021 08:15:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered empty.	System	13 Oct 2020 16:58:37

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered empty.	System	13 Oct 2020 16:58:37

US3552371

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered empty.	System	13 Oct 2020 16:58:37

US3552371

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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) (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) (b) (4)	13 Oct 2020 17:02:53

US3552371

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:08:38
User closed query 'Please add AE (Elevated liver enzymes) ' (Site from CRA).		18 Nov 2020 17:08:24
Query 'Please add AE (Elevated liver enzymes) ' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4) (b) (4)	18 Nov 2020 16:02:28
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	18 Nov 2020 16:02:10
User entered 'Elevated liver enzymes' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	18 Nov 2020 16:02:10
User opened query 'Please add AE (Elevated liver enzymes) ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 02:36:46
DataPoint Verified.		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: 10 Jun 2021 08:15:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered empty.	System	13 Oct 2020 17:02:53

US3552371

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	15 Oct 2020 19:43:39
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 19:43:39
	Stanley Doublin (b) (4)	13 Oct 2020 17:02:53
	(b) (4)	

US3552371

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered empty.	System	13 Oct 2020 17:02:53

US3552371

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
DataPoint Verified.		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: 10 Jun 2021 08:15:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered empty.	System	13 Oct 2020 17:02:53

US3552371

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:48
User entered '13 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	13 Oct 2020 17:03:46

US3552371

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
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: 10 Jun 2021 08:15:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:43:55
User entered '13 Oct 2020'	Stanley Dublin (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: 10 Jun 2021 08:15:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	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: 10 Jun 2021 08:15:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
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: 10 Jun 2021 08:15:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Dublin (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: 10 Jun 2021 08:15:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered empty.	System	13 Oct 2020 17:03:58

US3552371

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered 'I'	System	20 Oct 2020 17:43:50

US3552371

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	28 Oct 2020 20:55:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 20:55:20
	Stanley Doublin (b) (4)	20 Oct 2020 17:43:59
	(b) (4)	

US3552371

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 20:55:20
User entered empty.	Stanley Doublin (b) (4)	20 Oct 2020 17:43:59
	(b) (4)	

US3552371

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User entered 'l'	System	27 Oct 2020 15:18:40

US3552371

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:55:36
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	27 Oct 2020 15:18:52

US3552371

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 20:55:36
User entered '27 Oct 2020'	Stanley Doublin (b) (4)	27 Oct 2020 15:18:52
	(b) (4)	

US3552371

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	28 Oct 2020 20:55:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Oct 2020 20:55:36
	Stanley Doublin (b) (4)	27 Oct 2020 15:18:52
	(b) (4)	

US3552371

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 20:55:36
User entered empty.	Stanley Doublin (b) (4)	27 Oct 2020 15:18:52
	(b) (4)	

US3552371

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:25:24
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	03 Nov 2020 16:16:53

US3552371

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User entered 'l'	System	03 Nov 2020 16:16:53

US3552371

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	09 Nov 2020 16:26:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 16:26:01
	Stanley Doublin (b) (4)	03 Nov 2020 16:17:03
	(b) (4)	

US3552371

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	16 Nov 2020 00:51:51
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 00:51:51
	Mikayla Frye (b) (4)	10 Nov 2020 17:36:41
	(b) (4)	10 Nov 2020 17:36:41
User entered '03 Nov 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	10 Nov 2020 17:36:41
	(b) (4)	10 Nov 2020 17:36:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:26:01
	(b) (4)	09 Nov 2020 16:26:01
User entered '3 Nov 2020'	Stanley Dublin (b) (4)	03 Nov 2020 16:17:03
	(b) (4)	03 Nov 2020 16:17:03

US3552371

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	09 Nov 2020 16:26:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Nov 2020 16:26:01
	Stanley Dublin (b) (4)	03 Nov 2020 16:17:03
	(b) (4)	

US3552371

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	09 Nov 2020 16:26:01
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:26:01
	Stanley Doublin (b) (4)	03 Nov 2020 16:17:03
	(b) (4)	

US3552371

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 15:20:36
User entered 'Yes (Y)'	Stanley Dublin (b) (4)	10 Nov 2020 17:07:02
	(b) (4)	

US3552371

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:04
User entered 'I'	System	10 Nov 2020 17:07:02

US3552371

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:20:41
User entered '10 Nov 2020'	Stanley Dublin (b) (4) (b) (4)	10 Nov 2020 17:07:11

US3552371

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered 'VISIT3'	System	10 Nov 2020 17:07:11

US3552371

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:20:45
User entered empty.	Stanley Dublin (b) (4) (b) (4)	10 Nov 2020 17:07:17

US3552371

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:20:45
User entered empty.	Stanley Dublin (b) (4) (b) (4)	10 Nov 2020 17:07:17

US3552371

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered empty.	System	10 Nov 2020 17:07:17

US3552371

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:20:45
User entered empty.	Stanley Dublin (b) (4) (b) (4)	10 Nov 2020 17:07:17

US3552371

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:20:45
User entered empty.	Stanley Dublin (b) (4) (b) (4)	10 Nov 2020 17:07:17

US3552371

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:20:45
User entered empty.	Stanley Dublin (b) (4) (b) (4)	10 Nov 2020 17:07:17

US3552371

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:20:45
User entered empty.	Stanley Dublin (b) (4) (b) (4)	10 Nov 2020 17:07:17

US3552371

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered empty.	System	10 Nov 2020 17:07:17

US3552371

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:20:45
User entered empty.	Stanley Dublin (b) (4) (b) (4)	10 Nov 2020 17:07:17

US3552371

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered empty.	System	10 Nov 2020 17:07:17

US3552371

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:20:45
User entered empty.	Stanley Dublin (b) (4) (b) (4)	10 Nov 2020 17:07:17

US3552371

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered empty.	System	10 Nov 2020 17:07:17

US3552371

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:20:45
User entered empty.	Stanley Dublin (b) (4) (b) (4)	10 Nov 2020 17:07:17

US3552371

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered empty.	System	10 Nov 2020 17:07:17

US3552371

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22

US3552371

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22

US3552371

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:20:55
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	10 Nov 2020 17:07:23

US3552371

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:20:55
User entered empty.	Stanley Dublin (b) (4) (b) (4)	10 Nov 2020 17:07:23

US3552371

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered '10 Nov 2020 10:44'	System	10 Nov 2020 17:07:35

US3552371

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 04:18:01
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	08 Dec 2020 16:59:56

US3552371

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered 'I'	System	08 Dec 2020 16:59:56

US3552371

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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
	System	10 Nov 2020 16:38:17

US3552371

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[Please 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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:21:17
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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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' 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: 10 Jun 2021 08:15:53

[Have you been exposed to someone with 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' 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: 10 Jun 2021 08:15:53

[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

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: '2020-11-30T12:15:04', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '291f4ce8-8885-4a50-b401-6396873d2152'	System	30 Nov 2020 18:15:15
User entered 'No (N)'	System	30 Nov 2020 18:15:15

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[Have you been exposed to someone with 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: '2020-11-30T12:15:07', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '291f4ce8-8885-4a50-b401-6396873d2152'	System	30 Nov 2020 18:15:15
User entered 'No (N)'	System	30 Nov 2020 18:15:15

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: '2020-11-30T12:15:11', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '291f4ce8-8885-4a50-b401-6396873d2152' User entered '30 Nov 2020 12:15:11'	System	30 Nov 2020 18:15:15
	System	30 Nov 2020 18:15:15

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: '2020-12-07T12:50:04', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'ff7bb550-fc04-48e6-b141-e1c82bf344a7'	System	07 Dec 2020 18:50:14
User entered 'No (N)'	System	07 Dec 2020 18:50:14

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

Have you been exposed to someone with 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: '2020-12-07T12:50:07', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'ff7bb550-fc04-48e6-b141-e1c82bf344a7'	System	07 Dec 2020 18:50:14
User entered 'No (N)'	System	07 Dec 2020 18:50:14

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: '2020-12-07T12:50:10', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'ff7bb550-fc04-48e6-b141-e1c82bf344a7' User entered '07 Dec 2020 12:50:10'	System	07 Dec 2020 18:50:14
	System	07 Dec 2020 18:50:14

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: '2020-12-10T09:00:37', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'bec74f4a-a8db-4dd0-adf8-be3df50ad6d8'	System	10 Dec 2020 15:00:45
User entered 'No (N)'	System	10 Dec 2020 15:00:45

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

Have you been exposed to someone with 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: '2020-12-10T09:00:40', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'bec74f4a-a8db-4dd0-adf8-be3df50ad6d8'	System	10 Dec 2020 15:00:45
User entered 'No (N)'	System	10 Dec 2020 15:00:45

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: '2020-12-10T09:00:43', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'bec74f4a-a8db-4dd0-adf8-be3df50ad6d8' User entered '10 Dec 2020 09:00:43'	System	10 Dec 2020 15:00:45
	System	10 Dec 2020 15:00:45

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: '2020-12-17T16:39:10', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '09565f79-8d6e-45b4-bf15-b42884148ccd' User entered 'Yes (Y)'	System	17 Dec 2020 22:40:06
	System	17 Dec 2020 22:40:06

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[Have you been exposed to someone with 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: '2020-12-17T16:39:16', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '09565f79-8d6e-45b4-bf15-b42884148ccd' User entered 'No (N)'	System	17 Dec 2020 22:40:06

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: '2020-12-17T16:39:26', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '09565f79-8d6e-45b4-bf15-b42884148ccd' User entered 'No (N)'	System	17 Dec 2020 22:40:06

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: '2020-12-17T16:39:34', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '09565f79-8d6e-45b4-bf15-b42884148ccd' User entered 'Yes (Y)'	System	17 Dec 2020 22:40:06
	System	17 Dec 2020 22:40:06

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[Please 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: '2020-12-17T16:39:49', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '09565f79-8d6e-45b4-bf15-b42884148ccd'	System	17 Dec 2020 22:40:06
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Dec 2020 22:40:06

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: '2020-12-17T16:39:57', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '09565f79-8d6e-45b4-bf15-b42884148ccd' User entered '17 Dec 2020 16:39:57'	System	17 Dec 2020 22:40:06
	System	17 Dec 2020 22:40:06

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: '2020-12-24T09:03:25', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '07069c91-a749-41af-a651-918efba102ee' User entered 'No (N)'	System	24 Dec 2020 15:03:37

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[Have you been exposed to someone with 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: '2020-12-24T09:03:29', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '07069c91-a749-41af-a651-918efba102ee' User entered 'No (N)'	System	24 Dec 2020 15:03:37

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: '2020-12-24T09:03:33', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '07069c91-a749-41af-a651-918efba102ee' User entered '24 Dec 2020 09:03:33'	System	24 Dec 2020 15:03:37
	System	24 Dec 2020 15:03:37

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: '2021-01-02T23:48:02', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'b3a8baee-4ca5-4580-8a6f-f3878b00a629'	System	03 Jan 2021 05:48:23
User entered 'No (N)'	System	03 Jan 2021 05:48:23

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[Have you been exposed to someone with 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: '2021-01-02T23:48:10', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'b3a8baee-4ca5-4580-8a6f-f3878b00a629'	System	03 Jan 2021 05:48:23
User entered 'No (N)'	System	03 Jan 2021 05:48:23

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: '2021-01-02T23:48:17', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'b3a8baee-4ca5-4580-8a6f-f3878b00a629' User entered '02 Jan 2021 23:48:17'	System	03 Jan 2021 05:48:23
	System	03 Jan 2021 05:48:23

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: '2021-01-10T00:48:28', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '4b6ffda0-b2be-4ddd-a31a-01d926220360'	System	10 Jan 2021 06:48:38
User entered 'No (N)'	System	10 Jan 2021 06:48:38

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[Have you been exposed to someone with 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: '2021-01-10T00:48:32', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '4b6ffda0-b2be-4ddd-a31a-01d926220360'	System	10 Jan 2021 06:48:38
User entered 'No (N)'	System	10 Jan 2021 06:48:38

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: '2021-01-10T00:48:36', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '4b6ffda0-b2be-4ddd-a31a-01d926220360' User entered '10 Jan 2021 00:48:36'	System	10 Jan 2021 06:48:38
	System	10 Jan 2021 06:48:38

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: '2021-01-14T12:44:10', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '3876cbfe-18e4-424b-bea9-9131c722ec7f' User entered 'No (N)'	System	14 Jan 2021 18:44:50

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[Have you been exposed to someone with 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: '2021-01-14T12:44:30', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '3876cbfe-18e4-424b-bea9-9131c722ec7f' User entered 'No (N)'	System	14 Jan 2021 18:44:50

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: '2021-01-14T12:44:44', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '3876cbfe-18e4-424b-bea9-9131c722ec7f' User entered '14 Jan 2021 12:44:44'	System	14 Jan 2021 18:44:50
	System	14 Jan 2021 18:44:50

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: '2021-01-21T11:45:32', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'cd62c921-27d6-4e9b-8234-ac846dd060b3'	System	21 Jan 2021 17:45:40
User entered 'No (N)'	System	21 Jan 2021 17:45:40

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

Have you been exposed to someone with 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: '2021-01-21T11:45:35', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'cd62c921-27d6-4e9b-8234-ac846dd060b3'	System	21 Jan 2021 17:45:40
User entered 'No (N)'	System	21 Jan 2021 17:45:40

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: '2021-01-21T11:45:38', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'cd62c921-27d6-4e9b-8234-ac846dd060b3'	System	21 Jan 2021 17:45:40
User entered '21 Jan 2021 11:45:38'	System	21 Jan 2021 17:45:40

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: '2021-01-28T22:55:20', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '7f24e3bd-3341-4534-a9c7-25fc93684f57'	System	29 Jan 2021 04:55:31
User entered 'No (N)'	System	29 Jan 2021 04:55:31

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[Have you been exposed to someone with 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: '2021-01-28T22:55:24', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '7f24e3bd-3341-4534-a9c7-25fc93684f57'	System	29 Jan 2021 04:55:31
User entered 'No (N)'	System	29 Jan 2021 04:55:31

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: '2021-01-28T22:55:28', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '7f24e3bd-3341-4534-a9c7-25fc93684f57'	System	29 Jan 2021 04:55:31
User entered '28 Jan 2021 22:55:28'	System	29 Jan 2021 04:55:31

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: '2021-02-04T21:52:12', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'ddf0927a-07aa-4249-870c-6518cda03d06' User entered 'Yes (Y)'	System	05 Feb 2021 03:52:36

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

Have you been exposed to someone with 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: '2021-02-04T21:52:15', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'ddf0927a-07aa-4249-870c-6518cda03d06'	System	05 Feb 2021 03:52:36
User entered 'No (N)'	System	05 Feb 2021 03:52:36

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: '2021-02-04T21:52:19', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'ddf0927a-07aa-4249-870c-6518cda03d06' User entered 'No (N)'	System	05 Feb 2021 03:52:36

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: '2021-02-04T21:52:23', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'ddf0927a-07aa-4249-870c-6518cda03d06' User entered 'No (N)'	System	05 Feb 2021 03:52:36

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: '2021-02-04T21:52:29', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'ddf0927a-07aa-4249-870c-6518cda03d06' User entered '04 Feb 2021 21:52:29'	System	05 Feb 2021 03:52:36
	System	05 Feb 2021 03:52:36

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: '2021-02-13T00:32:28', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '7176065b-168d-419a-a6b9-31136d571cc0'	System	13 Feb 2021 06:32:42
User entered 'No (N)'	System	13 Feb 2021 06:32:42

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

Have you been exposed to someone with 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: '2021-02-13T00:32:33', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '7176065b-168d-419a-a6b9-31136d571cc0'	System	13 Feb 2021 06:32:42
User entered 'No (N)'	System	13 Feb 2021 06:32:42

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: '2021-02-13T00:32:40', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '7176065b-168d-419a-a6b9-31136d571cc0' User entered '13 Feb 2021 00:32:40'	System	13 Feb 2021 06:32:42
	System	13 Feb 2021 06:32:42

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: '2021-02-18T00:01:14', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'e91de2ca-45a3-4d6e-a698-936912fe3b53'	System	18 Feb 2021 06:01:48
User entered 'No (N)'	System	18 Feb 2021 06:01:48

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

Have you been exposed to someone with 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: '2021-02-18T00:01:22', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'e91de2ca-45a3-4d6e-a698-936912fe3b53'	System	18 Feb 2021 06:01:48
User entered 'No (N)'	System	18 Feb 2021 06:01:48

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: '2021-02-18T00:01:28', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'e91de2ca-45a3-4d6e-a698-936912fe3b53' User entered '18 Feb 2021 00:01:28'	System	18 Feb 2021 06:01:48
	System	18 Feb 2021 06:01:48

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: '2021-02-28T18:02:04', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '918942c2-0e67-4dbb-9ff0-74ae48882b75' User entered 'No (N)'	System	28 Feb 2021 23:07:03

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

Have you been exposed to someone with 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: '2021-02-28T18:02:07', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '918942c2-0e67-4dbb-9ff0-74ae48882b75'	System	28 Feb 2021 23:07:03
User entered 'No (N)'	System	28 Feb 2021 23:07:03

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: '2021-02-28T18:02:11', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '918942c2-0e67-4dbb-9ff0-74ae48882b75' User entered '28 Feb 2021 18:02:11'	System	28 Feb 2021 23:07:03
	System	28 Feb 2021 23:07:03

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: '2021-03-04T11:46:52', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '6125876d-bef0-4be3-abe6-2b457f795e29'	System	04 Mar 2021 17:47:13
User entered 'No (N)'	System	04 Mar 2021 17:47:13

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[Have you been exposed to someone with 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: '2021-03-04T11:47:00', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '6125876d-bef0-4be3-abe6-2b457f795e29' User entered 'No (N)'	System	04 Mar 2021 17:47:13

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: '2021-03-04T11:47:09', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '6125876d-bef0-4be3-abe6-2b457f795e29' User entered '04 Mar 2021 11:47:09'	System	04 Mar 2021 17:47:13
	System	04 Mar 2021 17:47:13

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: '2021-03-11T11:45:46', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '8d7ec339-3791-48cd-842c-0a3fae40dc61' User entered 'No (N)'	System	11 Mar 2021 17:45:56

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[Have you been exposed to someone with 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: '2021-03-11T11:45:49', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '8d7ec339-3791-48cd-842c-0a3fae40dc61' User entered 'No (N)'	System	11 Mar 2021 17:45:56

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: '2021-03-11T11:45:53', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '8d7ec339-3791-48cd-842c-0a3fae40dc61' User entered '11 Mar 2021 11:45:53'	System	11 Mar 2021 17:45:56
	System	11 Mar 2021 17:45:56

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: '2021-03-18T14:43:58', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '14a06d2d-f52a-4717-b7ac-7ef07796d819'	System	18 Mar 2021 19:44:28
User entered 'No (N)'	System	18 Mar 2021 19:44:28

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

Have you been exposed to someone with 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: '2021-03-18T14:44:04', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '14a06d2d-f52a-4717-b7ac-7ef07796d819'	System	18 Mar 2021 19:44:28
User entered 'Yes (Y)'	System	18 Mar 2021 19:44:28

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[Please 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: '2021-03-18T14:44:12', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '14a06d2d-f52a-4717-b7ac-7ef07796d819'	System	18 Mar 2021 19:44:28
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Mar 2021 19:44:28

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: '2021-03-18T14:44:18', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '14a06d2d-f52a-4717-b7ac-7ef07796d819' User entered '18 Mar 2021 14:44:18'	System	18 Mar 2021 19:44:28
	System	18 Mar 2021 19:44:28

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: '2021-03-25T11:46:44-05:00', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '06ba1b0c-a2fa-4971-a44d-152a2f186e5e'	System	25 Mar 2021 16:46:56
User entered 'No (N)'	System	25 Mar 2021 16:46:56

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[Have you been exposed to someone with 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: '2021-03-25T11:46:50-05:00', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '06ba1b0c-a2fa-4971-a44d-152a2f186e5e'	System	25 Mar 2021 16:46:56
User entered 'No (N)'	System	25 Mar 2021 16:46:56

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: '2021-03-25T11:46:53-05:00', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '06ba1b0c-a2fa-4971-a44d-152a2f186e5e' User entered '25 Mar 2021 11:46:53'	System	25 Mar 2021 16:46:56
	System	25 Mar 2021 16:46:56

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: '2021-04-01T11:45:27-05:00', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'a547e456-e8be-4828-b1d0-e4a26fd47d77'	System	01 Apr 2021 16:45:41
User entered 'No (N)'	System	01 Apr 2021 16:45:41

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

Have you been exposed to someone with 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: '2021-04-01T11:45:32-05:00', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'a547e456-e8be-4828-b1d0-e4a26fd47d77'	System	01 Apr 2021 16:45:41
User entered 'No (N)'	System	01 Apr 2021 16:45:41

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: '2021-04-01T11:45:35-05:00', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'a547e456-e8be-4828-b1d0-e4a26fd47d77'	System	01 Apr 2021 16:45:41
User entered '01 Apr 2021 11:45:35'	System	01 Apr 2021 16:45:41

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: '2021-04-08T09:08:59-05:00', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'ef9df61d-ebf1-47b6-ace5-b99c167e9bfb' User entered 'No (N)'	System	08 Apr 2021 14:09:15

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

Have you been exposed to someone with 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: '2021-04-08T09:09:01-05:00', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'ef9df61d-ebf1-47b6-ace5-b99c167e9bfb' User entered 'No (N)'	System	08 Apr 2021 14:09:15

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: '2021-04-08T09:09:07-05:00', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'ef9df61d-ebf1-47b6-ace5-b99c167e9bfb' User entered '08 Apr 2021 09:09:07'	System	08 Apr 2021 14:09:15
	System	08 Apr 2021 14:09:15

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: '2021-04-18T00:04:23-05:00', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '42af6d6a-4739-4171-91f7-2dfb05330c8c' User entered 'No (N)'	System	18 Apr 2021 05:04:32

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[Have you been exposed to someone with 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: '2021-04-18T00:04:27-05:00', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '42af6d6a-4739-4171-91f7-2dfb05330c8c'	System	18 Apr 2021 05:04:32
User entered 'No (N)'	System	18 Apr 2021 05:04:32

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: '2021-04-18T00:04:29-05:00', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '42af6d6a-4739-4171-91f7-2dfb05330c8c' User entered '18 Apr 2021 00:04:29'	System	18 Apr 2021 05:04:32
	System	18 Apr 2021 05:04:32

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: '2021-04-22T09:00:23-05:00', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'c6f7e78d-c368-4225-927e-44bcab2f0c40'	System	22 Apr 2021 14:00:37
User entered 'No (N)'	System	22 Apr 2021 14:00:37

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[Have you been exposed to someone with 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: '2021-04-22T09:00:28-05:00', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'c6f7e78d-c368-4225-927e-44bcab2f0c40'	System	22 Apr 2021 14:00:37
User entered 'No (N)'	System	22 Apr 2021 14:00:37

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: '2021-04-22T09:00:31-05:00', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: 'c6f7e78d-c368-4225-927e-44bcab2f0c40'	System	22 Apr 2021 14:00:37
User entered '22 Apr 2021 09:00:31'	System	22 Apr 2021 14:00:37

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: '2021-04-29T11:52:17-05:00', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '5eebff78-a1b1-4e96-ad91-db02caddbcda' User entered 'No (N)'	System	29 Apr 2021 16:52:26

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

Have you been exposed to someone with 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: '2021-04-29T11:52:20-05:00', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '5eebff78-a1b1-4e96-ad91-db02caddbcda' User entered 'No (N)'	System	29 Apr 2021 16:52:26

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: '2021-04-29T11:52:23-05:00', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '5eebff78-a1b1-4e96-ad91-db02caddbcda' User entered '29 Apr 2021 11:52:23'	System	29 Apr 2021 16:52:26
	System	29 Apr 2021 16:52:26

US3552371

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:15:53

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:34:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2021-02-28T18:02:17', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '78bd69ee-e87c-4d58-862e-6824a6a9e305'	System	28 Feb 2021 23:07:22
User entered 'No (N)'	System	28 Feb 2021 23:07:22

US3552371

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:15:53

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:34:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FCF1B0C1-1575-4572-8878-EE41C04A6B6F)', Time: '2021-02-28T18:02:22', User OID: 'PatientReportedOutcome (US3552371)', ODM File OID: '78bd69ee-e87c-4d58-862e-6824a6a9e305' User entered '28 Feb 2021 18:02:22'	System	28 Feb 2021 23:07:22
	System	28 Feb 2021 23:07:22

US3552371

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:50:00
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	08 Dec 2020 17:00:29

US3552371

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:50:00
User entered '08 Dec 2020'	Stanley Doublin (b) (4) (b) (4)	08 Dec 2020 17:00:29

US3552371

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:50:00
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4) (b) (4)	08 Dec 2020 17:00:29

US3552371

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:50:00
User entered empty.	Stanley Doublin (b) (4) (b) (4)	08 Dec 2020 17:00:29

US3552371

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:50:53
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	12 Jan 2021 13:05:55

US3552371

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:46:22
User entered 'I'	System	12 Jan 2021 13:05:55

US3552371

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	21 Jan 2021 20:50:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Jan 2021 20:50:57
	Stanley Doublin (b) (4)	12 Jan 2021 13:06:08
	(b) (4)	

US3552371

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	21 Jan 2021 20:50:57
User entered '11 Jan 2021'	(b) (4), (b) (6)	21 Jan 2021 20:50:57
	Stanley Doublin (b) (4)	12 Jan 2021 13:06:08
	(b) (4)	

US3552371

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	21 Jan 2021 20:50:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	21 Jan 2021 20:50:57
	Stanley Doublin (b) (4)	12 Jan 2021 13:06:08
	(b) (4)	

US3552371

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	21 Jan 2021 20:50:57
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 20:50:57
	Stanley Doublin (b) (4)	12 Jan 2021 13:06:08
	(b) (4)	

US3552371

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:56
DataPoint Verified.		18 Mar 2021 17:01:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Feb 2021 20:45:49

US3552371

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:56
User entered 'I'	System	10 Feb 2021 20:45:49

US3552371

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:56
DataPoint Verified.		18 Mar 2021 17:08:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Feb 2021 20:45:58

US3552371

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:56
DataPoint Verified.		18 Mar 2021 17:08:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
User entered '10 Feb 2021'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Feb 2021 20:45:58

US3552371

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:56
DataPoint Verified.		18 Mar 2021 17:08:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Feb 2021 20:45:58

US3552371

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:56
DataPoint Verified.		18 Mar 2021 17:08:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	10 Feb 2021 20:45:58

US3552371

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:56
DataPoint Verified.		18 Mar 2021 17:08:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	11 Feb 2021 22:36:29

US3552371

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:56
User entered 'I'	System	11 Feb 2021 22:36:29

US3552371

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:56
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:38:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 17:08:50
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	12 Mar 2021 17:00:42
	(b) (4)	

US3552371

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:56
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:38:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 17:08:50
User entered '12 Mar 2021'	Stanley Doublin (b) (4)	12 Mar 2021 17:00:42
	(b) (4)	

US3552371

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:56
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:38:48
DataPoint Verified.	(b) (4)	18 Mar 2021 17:08:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	18 Mar 2021 17:08:50
	Stanley Doublin (b) (4)	12 Mar 2021 17:00:42
	(b) (4)	

US3552371

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:56
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:38:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 17:08:50
User entered empty.	Stanley Doublin (b) (4)	12 Mar 2021 17:00:42
	(b) (4)	

US3552371

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:56
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:38:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 17:08:53
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	12 Mar 2021 17:00:47
	(b) (4)	

US3552371

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:46:56
User entered 'l'	System	12 Mar 2021 17:00:47

US3552371

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:23
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 15:57:33

US3552371

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:23
User entered '13 Apr 2021'	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 15:57:33

US3552371

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:23
User entered 'Clinic (Clinic)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 15:57:33

US3552371

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:53

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	13 Apr 2021 15:57:33

US3552371

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:23
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 15:57:36

US3552371

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:23
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 15:57:36

US3552371

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:23
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 15:57:36

US3552371

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 15:57:36

US3552371

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:23
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 15:57:36

US3552371

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:23
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 15:57:36

US3552371

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:23
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 15:57:36

US3552371

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:23
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 15:57:36

US3552371

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 15:57:36

US3552371

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:23
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 15:57:36

US3552371

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 15:57:36

US3552371

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:23
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 15:57:36

US3552371

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 15:57:36

US3552371

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:23
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 15:57:36

US3552371

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 15:57:36

US3552371

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:53

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:23
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 15:57:42

US3552371

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:53

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:23
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 15:57:42

US3552371

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:23
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 15:57:50

US3552371

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:23
User entered '13 Apr 2021'	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 15:57:50

US3552371

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:23
User entered '10:38'	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 15:57:50

US3552371

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
User entered '13 Apr 2021 10:38'	System	13 Apr 2021 15:57:50

US3552371

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:03:23
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Apr 2021 15:57:52

US3552371

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:53

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'l'	System	13 Apr 2021 15:57:52

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:09:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:48:40

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:09:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered '04 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:48:40

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:09:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:48:40

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
User entered 'UNBLND_DECIDE'	System	04 Feb 2021 17:48:40

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:15:53

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:09:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered '04 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:48:57

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:15:53

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:38:48
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:54:05

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:15:53

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:09:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:48:57

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:15:53

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:38:48
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:54:05

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:15:53

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:09:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered '04 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:48:57

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:15:53

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:09:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:48:57

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:15:53

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:09:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	04 Feb 2021 17:48:57

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:15:53

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.	(b) (4)	18 Mar 2021 17:09:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered 'Not Administered (NA)' reason for change: Data Entry Error	(b) (4)	
	Stanley Doublin (b) (4)	04 Feb 2021 17:51:11
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	
	Stanley Doublin (b) (4)	04 Feb 2021 17:48:57
	(b) (4)	

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:15:53

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:09:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Stanley Doublin (b) (4)	04 Feb 2021 17:51:11
User entered 'No (N)'	(b) (4)	
	Stanley Doublin (b) (4)	04 Feb 2021 17:48:57
	(b) (4)	

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:15:53

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
User entered empty.	System	04 Feb 2021 17:48:57

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:15:53

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
User entered 'I'	System	04 Feb 2021 17:51:11
User entered empty.	System	04 Feb 2021 17:48:57

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:15:53

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:16:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:51:54

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:15:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:16:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:51:54

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:15:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
User entered empty.	System	04 Feb 2021 17:51:54
DataPoint set to visible.	System	04 Feb 2021 17:51:11

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:15:53

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:16:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:51:54

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:15:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:16:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:51:54

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:15:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
User entered empty.	System	04 Feb 2021 17:51:54
DataPoint set to visible.	System	04 Feb 2021 17:51:11

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	04 Feb 2021 17:51:54

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.	(b) (4)	18 Mar 2021 17:16:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:51:54

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:53

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:16:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered '04 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:51:54

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:16:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered '09:30'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:51:54

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
User entered '04 Feb 2021 09:30'	System	04 Feb 2021 17:51:54

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:16:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered '98.3' F	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:51:54

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:16:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered 'Oral (Oral)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:51:54

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:16:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:51:54

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:16:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered '87'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:51:54

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
User entered 'bpm'	System	04 Feb 2021 17:51:54

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:16:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered '17'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:51:54

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
User entered 'breaths/min'	System	04 Feb 2021 17:51:54

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:16:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered '114'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:51:54

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
User entered 'mmHg'	System	04 Feb 2021 17:51:54

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:16:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered '77'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:51:54

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
User entered 'mmHg'	System	04 Feb 2021 17:51:54

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:15:53

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:16:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:51:54

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:15:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:16:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:51:54

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:15:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
User entered empty.	System	04 Feb 2021 17:51:54
DataPoint set to visible.	System	04 Feb 2021 17:51:11

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	04 Feb 2021 17:52:23

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:16:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:52:23

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:16:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered '04 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:52:23

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:16:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered '10:37'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:52:23

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
User entered '04 Feb 2021 10:37'	System	04 Feb 2021 17:52:23

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.	(b) (4)	18 Mar 2021 17:16:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered '98.4' F	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:52:23

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:16:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered 'Oral (Oral)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:52:23

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:16:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:52:23

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:16:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered '83'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:52:23

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
User entered 'bpm'	System	04 Feb 2021 17:52:23

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:16:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered '16'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:52:23

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
User entered 'breaths/min'	System	04 Feb 2021 17:52:23

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:16:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered '108'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:52:23

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
User entered 'mmHg'	System	04 Feb 2021 17:52:23

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:16:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered '73'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:52:23

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
User entered 'mmHg'	System	04 Feb 2021 17:52:23

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:16:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:52:44

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:16:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered '04 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:52:44

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:15:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.	(b) (4)	18 Mar 2021 17:17:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:53:00

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:15:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:17:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:53:00

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:17:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:53:00

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:15:53

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
User entered 'mRNA-1273'	System	04 Feb 2021 17:53:00
DataPoint set to visible.	System	04 Feb 2021 17:51:11

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:15:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:17:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered '04 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:53:00

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.	(b) (4)	18 Mar 2021 17:17:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered '10:07'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:53:00

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
User entered '04 Feb 2021 10:07'	System	04 Feb 2021 17:53:00

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:17:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered 'Left Arm (LEFT ARM)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:53:00

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:17:08
User entered 'ONCE'	System	04 Feb 2021 17:53:00

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:15:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
User entered 'INTRAMUSCULAR'	System	04 Feb 2021 17:53:00

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:17:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:49:14

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:17:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered '04 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:49:14

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:17:23
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered '09:15'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:49:14

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
User entered '04 Feb 2021 09:15'	System	04 Feb 2021 17:49:14

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:15:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:17:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:49:27

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:15:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:17:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered '04 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:49:27

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:15:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:17:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered '09:19'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Feb 2021 17:49:27

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
User entered '04 Feb 2021 09:19'	System	04 Feb 2021 17:49:27

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
DataPoint Verified.		18 Mar 2021 17:17:30
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	11 Feb 2021 17:41:39

US3552371

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:35
User entered 'I'	System	11 Feb 2021 17:41:39

US3552371

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:54
DataPoint Verified.		18 Mar 2021 17:17:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	11 Feb 2021 17:41:51

US3552371

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:54
DataPoint Verified.		18 Mar 2021 17:17:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
User entered '11 Feb 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	11 Feb 2021 17:41:51

US3552371

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:54
DataPoint Verified.		18 Mar 2021 17:17:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Heather Douds (b) (4) (b) (4)	11 Feb 2021 17:41:51

US3552371

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:54
DataPoint Verified.		18 Mar 2021 17:17:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	11 Feb 2021 17:41:51

US3552371

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:54
DataPoint Verified.		18 Mar 2021 17:17:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	11 Feb 2021 22:36:39

US3552371

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:54
User entered 'l'	System	11 Feb 2021 22:36:39

US3552371

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:53

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:51:54
User entered 'I'	System	11 Feb 2021 22:36:39
DataPoint set to visible.	System	11 Feb 2021 22:36:39

US3552371

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
DataPoint Verified.		18 Mar 2021 17:17:52
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:01:18
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	03 Mar 2021 19:56:02

US3552371

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
DataPoint Verified.		18 Mar 2021 17:17:52
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:01:18
User entered '3 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	03 Mar 2021 19:56:02

US3552371

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:17:52
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:01:18
User entered 'Clinic (Clinic)'	(b) (4) Heather Douds (b) (4) (b) (4)	03 Mar 2021 19:56:02

US3552371

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered 'OLD29'	System	03 Mar 2021 19:56:02

US3552371

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
DataPoint Verified.		18 Mar 2021 17:17:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:01:18
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	03 Mar 2021 19:56:08

US3552371

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
DataPoint Verified.		18 Mar 2021 17:17:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:01:18
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	03 Mar 2021 19:56:08

US3552371

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
DataPoint Verified.		18 Mar 2021 17:17:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:01:18
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	03 Mar 2021 19:56:08

US3552371

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered empty.	System	03 Mar 2021 19:56:08

US3552371

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
DataPoint Verified.		18 Mar 2021 17:17:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:01:18
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	03 Mar 2021 19:56:08

US3552371

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
DataPoint Verified.		18 Mar 2021 17:17:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:01:18
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	03 Mar 2021 19:56:08

US3552371

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
DataPoint Verified.		18 Mar 2021 17:17:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:01:18
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	03 Mar 2021 19:56:08

US3552371

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
DataPoint Verified.		18 Mar 2021 17:17:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:01:18
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	03 Mar 2021 19:56:08

US3552371

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered empty.	System	03 Mar 2021 19:56:08

US3552371

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
DataPoint Verified.		18 Mar 2021 17:17:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:01:18
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	03 Mar 2021 19:56:08

US3552371

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered empty.	System	03 Mar 2021 19:56:08

US3552371

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
DataPoint Verified.		18 Mar 2021 17:17:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:01:18
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	03 Mar 2021 19:56:08

US3552371

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered empty.	System	03 Mar 2021 19:56:08

US3552371

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
DataPoint Verified.		18 Mar 2021 17:17:56
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:01:18
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	03 Mar 2021 19:56:08

US3552371

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered empty.	System	03 Mar 2021 19:56:08

US3552371

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01

US3552371

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01

US3552371

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
DataPoint Verified.		18 Mar 2021 17:18:00
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:01:18
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	03 Mar 2021 19:56:13

US3552371

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:18:00
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:01:18
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	03 Mar 2021 19:56:13

US3552371

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
DataPoint Verified.		18 Mar 2021 17:18:04
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:01:18
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	03 Mar 2021 19:56:25

US3552371

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 03MAR2021 is recorded under Participant Decision Visit / OL-D29 in EDC, however the same is reported under OL-3 D57 visit in PPD Central lab. Please reconcile the correct Visit and confirm in query response. Else clarify, Thank you' (Site from DM).		24 Mar 2021 08:41:03
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:18:04
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 03MAR2021 is recorded under Participant Decision Visit / OL-D29 in EDC, however the same is reported under OL-3 D57 visit in PPD Central lab. Please reconcile the correct Visit and confirm in query response. Else clarify, Thank you' answered with 'subject only needed one dose in part B so OL D29 was basically 'OL D57" because no vaccination given' (Site from DM).	Cassandra Zehenny (b) (4)	17 Mar 2021 18:11:48
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 03MAR2021 is recorded under Participant Decision Visit / OL-D29 in EDC, however the same is reported under OL-3 D57 visit in PPD Central lab. Please reconcile the correct Visit and confirm in query response. Else clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 08:15:53
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:01:18
User entered '3 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	03 Mar 2021 19:56:25

US3552371

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
DataPoint Verified.		18 Mar 2021 17:18:04
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 17:01:18
User entered '10:42'	(b) (4) Heather Douds (b) (4) (b) (4)	03 Mar 2021 19:56:25

US3552371

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:09:01
User entered '3 Mar 2021 10:42'	System	03 Mar 2021 19:56:25

US3552371

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:15:53

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:33
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 04:03:35
User entered 'Yes (Y)'	Joan Siegner (b) (4) (b) (4)	28 Sep 2020 13:30:32

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:15:53

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:15:53

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User closed query 'Please update to include elevated liver enzymes ' (Site from CRA).		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).		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).		15 Oct 2020 19:41:10
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: 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: 10 Jun 2021 08:15:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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: 10 Jun 2021 08:15:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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: 10 Jun 2021 08:15:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered 'No (N)'	Joan Siegner (b) (4) (b) (4)	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:15:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:53

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37
User entered empty.	System	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:15:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:27:41
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	19 Nov 2020 17:34:05
User entered 'No (N)' reason for change: New Information	Cassandra Zehenny (b) (4) (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) (b) (4)	28 Sep 2020 13:35:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:15:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:27:43
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	19 Nov 2020 17:34:05
User entered '19 Nov 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	19 Nov 2020 17:34:05
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered empty.	Joan Siegner (b) (4) (b) (4)	28 Sep 2020 13:35:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:15:53

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37
User entered empty.	System	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:15:53

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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: 10 Jun 2021 08:15:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	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.'	Joan Siegner (b) (4)	28 Sep 2020 13:36:12
answered with 'Treatment in ER makes this a grade 4: no admission to the hospital; not an SAE' (Site from System).		
User opened query 'AE severity is Grade 4, but is the System 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: 10 Jun 2021 08:15:53

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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: 10 Jun 2021 08:15:53

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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: 10 Jun 2021 08:15:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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: 10 Jun 2021 08:15:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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: 10 Jun 2021 08:15:53

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:53

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	09 Nov 2020 16:41:02
User entered 'None (NONE)'	(b) (4), (b) (6)	09 Nov 2020 16:41:02
	Joan Siegner (b) (4)	28 Sep 2020 13:35:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:15:53

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered '0'	Joan Siegner (b) (4)	28 Sep 2020 13:35:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:15:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	09 Nov 2020 16:41:02
User entered 'l'	Joan Siegner (b) (4)	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:15:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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:	Cassandra Zehenny (b) (4)	19 Nov 2020 17:34:05
New Information	(b) (4)	
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: 10 Jun 2021 08:15:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered empty.	Joan Siegner (b) (4)	28 Sep 2020 13:35:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:15:53

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
User closed query 'Per DM CLR: Narrative indicates that the subject had a FALL that resulted to this AE. However, there is no corresponding AE record of Fall that match the information. Please update to record the corresponding AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 05:59:13
Query 'Per DM CLR: Narrative indicates that the subject had a FALL that resulted to this AE. However, there is no corresponding AE record of Fall that match the information. Please update to record the corresponding AE as appropriate. Otherwise, clarify.' answered with 'Fall not considered separate AE since ankle fracture is captured' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	19 Jan 2021 19:16:14
User opened query 'Per DM CLR: Narrative indicates that the subject had a FALL that resulted to this AE. However, there is no corresponding AE record of Fall that match the information. Please update to record the corresponding AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 14:13:21
User closed query 'Per DM CLR: SAE Narrative = SUBJECT FELL OFF. However, please review and verify if FALL should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 05:25:19
Query 'Per DM CLR: SAE Narrative = SUBJECT FELL OFF. However, please review and verify if FALL should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'correct as entered' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	29 Dec 2020 22:48:55
User opened query 'Per DM CLR: SAE Narrative = SUBJECT FELL OFF. However, please review and verify if FALL should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Dec 2020 21:57:35
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:15:53

[Narrative](#)

Audit	User	Time (GMT)
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) [REDACTED]	28 Sep 2020 13:35:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:15:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37
User entered '0'	System	28 Sep 2020 13:35:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:15:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37
User entered 'I'	System	28 Sep 2020 13:35:23

US3552371

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:15:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:41:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:53

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:53

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User coded data point as SOC: Investigations, HLGT: Hepatobiliary investigations, HLT: Liver function analyses, PT: Hepatic enzyme increased, LLT: Elevated liver enzymes - version MedDRA\\23.0.	Coder Import (b) (4) (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) (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) (b) (4)	19 Oct 2020 18:18:29

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06
User entered empty.	System	19 Oct 2020 18:18:29

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	21 Jan 2021 20:53:28
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 20:53:28
	Cassandra Zehenny (b) (4)	17 Dec 2020 22:45:17
User entered 'No (N)' reason for change: New Information	(b) (4)	17 Dec 2020 22:45:17
DataPoint Verified.	Cassandra Zehenny (b) (4)	09 Nov 2020 16:41:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 18:18:29
	Cassandra Zehenny (b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	21 Jan 2021 20:53:29
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 20:53:29
	Cassandra Zehenny (b) (4)	17 Dec 2020 22:45:17
User entered '17 Dec 2020' reason for change: Data Entry Error	(b) (4)	17 Dec 2020 22:45:17
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: 10 Jun 2021 08:15:53

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06
User entered empty.	System	19 Oct 2020 18:18:29

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:53

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered 'Grade 3/Severe (Grade 3/Severe)'	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: 10 Jun 2021 08:15:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:15:53

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:53

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:53

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered '0'	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: 10 Jun 2021 08:15:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered '0'	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: 10 Jun 2021 08:15:53

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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).	(b) (4)	
	System	19 Oct 2020 18:18:29
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: 10 Jun 2021 08:15:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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).	(b) (4)	
	System	19 Oct 2020 18:18:29
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: 10 Jun 2021 08:15:53

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	09 Nov 2020 16:41:02
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	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).	(b) (4)	19 Oct 2020 18:18:29
User entered empty.	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: 10 Jun 2021 08:15:53

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	19 Oct 2020 18:18:29
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: 10 Jun 2021 08:15:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:53

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	21 Jan 2021 20:53:33
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 20:53:33
	Cassandra Zehenny (b) (4)	17 Dec 2020 22:45:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4)	17 Dec 2020 22:45:17
DataPoint Verified.	Cassandra Zehenny (b) (4)	17 Dec 2020 22:45:17
	(b) (4)	
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).	(b) (4), (b) (6)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	02 Nov 2020 17:35:17
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)	
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).	Cassandra Zehenny (b) (4)	02 Nov 2020 17:35:13
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Nov 2020 02:58:19
Query 'Data is required. Please complete.' answered with 'AE not resolved yet' (Site from System).	(b) (4), (b) (6)	02 Nov 2020 02:58:19
	(b) (4), (b) (6)	02 Nov 2020 02:58:19
	(b) (4), (b) (6)	02 Nov 2020 02:56:15
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 16:09:01
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	Joan Siegner (b) (4)	30 Oct 2020 16:08:52
	(b) (4)	
	System	30 Oct 2020 16:08:19

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
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: 10 Jun 2021 08:15:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	19 Oct 2020 18:18:29

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	19 Oct 2020 18:18:29

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Folder: Adverse Events

Form: Adverse Events (2)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06
User entered '0'	System	19 Oct 2020 18:18:29

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Folder: Adverse Events

Form: Adverse Events (2)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06
User entered 'I'	System	19 Oct 2020 18:18:29

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:34:06

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Folder: Adverse Events

Form: Adverse Events (3)

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[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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)

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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)	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)	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)	20 Nov 2020 19:44:32
	(b) (4)	
Coding entries removed.	Cassandra Zehenny (b) (4)	20 Nov 2020 19:44:32
	(b) (4)	
User entered 'RIGHT kidney renal cell carcinoma' reason for change: New Information	Cassandra Zehenny (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).		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)	20 Oct 2020 21:03:36
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (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)	20 Oct 2020 21:02:39
	(b) (4)	

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Folder: Adverse Events

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 21:02:39

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Folder: Adverse Events

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered 'No (N)'	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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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 15:34:42
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	20 Nov 2020 17:36:07
	(b) (4)	
User entered '08 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	20 Nov 2020 17:36:07
	(b) (4)	
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: 10 Jun 2021 08:15:53

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:41:02
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 21:02:39

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Folder: Adverse Events

Form: Adverse Events (3)

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[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: 10 Jun 2021 08:15:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 15:34:51
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	20 Nov 2020 17:36:40
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Cassandra Zehenny (b) (4)	20 Nov 2020 17:36:40
	(b) (4)	
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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Form: Adverse Events (3)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
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.		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, System 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, System 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, System 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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Form: Adverse Events (3)

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End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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)

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[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)

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Severity

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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)	
	Cassandra Zehenny (b) (4)	20 Nov 2020 17:36:40
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 '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)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
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) (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) (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).		22 Nov 2020 16:08:44
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	19 Nov 2020 19:37:14
User entered 'Yes (Y)' reason for change: New Information	Cassandra Zehenny (b) (4) (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) (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) (b) (4)	20 Oct 2020 21:02:39

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
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
	(b) (4)	

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
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
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	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).	(b) (4), (b) (6)	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)	19 Nov 2020 19:37:14
DataPoint Verified.	Cassandra Zehenny (b) (4)	09 Nov 2020 16:41:02
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 21:02:39
	Cassandra Zehenny (b) (4)	

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Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 15:34:17
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	19 Nov 2020 19:37:14
	(b) (4)	
User entered '12 Nov 2020' reason for change: New Information	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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Form: Adverse Events (3)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 15:34:20
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	19 Nov 2020 19:37:14
	(b) (4)	
User entered '13 Nov 2020' reason for change: New Information	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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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 15:34:22
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	19 Nov 2020 19:39:17
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Cassandra Zehenny (b) (4)	19 Nov 2020 19:39:17
	(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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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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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Form: Adverse Events (3)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
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
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
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

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
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
	(b) (4)	

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Form: Adverse Events (3)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4) (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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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 20:18:34
DataPoint Un-verified.	Stanley Doublin (b) (4)	23 Nov 2020 17:55:52
	(b) (4)	
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
	(b) (4)	

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None

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	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).	(b) (4), (b) (6)	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)	(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)	20 Nov 2020 17:36:07
DataPoint Verified.	System	09 Nov 2020 16:41:02
User entered '1'	(b) (4), (b) (6)	20 Oct 2020 21:02:39
	Cassandra Zehenny (b) (4)	
	(b) (4)	

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Folder: Adverse Events

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Generated On: 10 Jun 2021 08:15:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	21 Jan 2021 20:53:48
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 11:23:32
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	19 Jan 2021 19:19:07
User entered '0' reason for change: Per Query Resolution	(b) (4)	19 Jan 2021 19:17:10
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	Cassandra Zehenny (b) (4)	19 Jan 2021 19:17:10
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 14:13:40
DataPoint Un-verified.	(b) (4)	23 Nov 2020 15:34:27
User entered '1' reason for change: New Information	Cassandra Zehenny (b) (4)	20 Nov 2020 17:37:19
DataPoint Verified.	(b) (4)	20 Nov 2020 17:37:19
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 16:41:02
	Cassandra Zehenny (b) (4)	20 Oct 2020 21:02:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 15:34:29
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	20 Nov 2020 17:36:07
	(b) (4)	
User entered '1' reason for change: New Information	Cassandra Zehenny (b) (4)	20 Nov 2020 17:36:07
	(b) (4)	
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
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:53

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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).		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).		02 Nov 2020 02:55:44
User closed query 'Data is required. Please complete.' (Site from System).		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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:53

[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) (b) (4)	20 Oct 2020 21:02:39

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Folder: Adverse Events

Form: Adverse Events (3)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:53

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User closed query 'PV Query: Please send a hospital discharge summary and surgical path report with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 13:20:18
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).		01 Dec 2020 13:20:13
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'No COVID testing done ' (Site from Safety).	Cassandra Zehenny (b) (4)	30 Nov 2020 18:57:57
Query 'PV Query: Please send a hospital discharge summary and surgical path report with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Records were sent on 20Nov at 1343. Thanks. ' (Site from Safety).	Cassandra Zehenny (b) (4)	30 Nov 2020 18:57:50
User opened query 'PV Query: Please send a hospital discharge summary and surgical path report with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 21:48:36
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).		25 Nov 2020 21:47:58
DataPoint Verified.		23 Nov 2020 20:18:44

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:53

[Narrative](#)

Audit	User	Time (GMT)
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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:53

[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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	20 Oct 2020 21:02:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 19:39:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:53

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:53

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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)	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)	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)	27 Oct 2020 16:45:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:06:48
User entered 'No (N)'	Mikayla Frye (b) (4)	27 Oct 2020 16:45:29

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	28 Oct 2020 21:06:42
User entered '22 Oct 2020'	(b) (4), (b) (6)	
	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: 10 Jun 2021 08:15:53

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09
User entered empty.	System	27 Oct 2020 16:45:29

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:31:23
User entered 'No (N)' reason for change: Data Entry Error	Stanley Dublin (b) (4)	03 Nov 2020 16:27:05
User entered 'Yes (Y)'	(b) (4)	
	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: 10 Jun 2021 08:15:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:31:24
User entered '29 Oct 2020' reason for change: Data Entry Error	Stanley Dublin (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)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:53

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:31:26
User entered empty.	Mikayla Frye (b) (4)	27 Oct 2020 16:45:29

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Folder: Adverse Events

Form: Adverse Events (4)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09
User entered empty.	System	27 Oct 2020 16:45:29

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:53

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:31:28
User entered 'Grade 1/Mild (Grade 1/Mild)'	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: 10 Jun 2021 08:15:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:31:30
User entered 'No (N)'	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: 10 Jun 2021 08:15:53

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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

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Folder: Adverse Events

Form: Adverse Events (4)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:31:37
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: 10 Jun 2021 08:15:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	09 Nov 2020 16:31:38
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 16:31:38
	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: 10 Jun 2021 08:15:53

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	09 Nov 2020 16:31:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:31:40
	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: 10 Jun 2021 08:15:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:31:41
User entered empty.	Mikayla Frye (b) (4)	27 Oct 2020 16:45:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:31:42
User entered empty.	Mikayla Frye (b) (4)	27 Oct 2020 16:45:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:31:44
User entered empty.	Mikayla Frye (b) (4)	27 Oct 2020 16:45:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	09 Nov 2020 16:31:45
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)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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

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Folder: Adverse Events

Form: Adverse Events (4)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	09 Nov 2020 16:31:48
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)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	09 Nov 2020 16:31:50
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Nov 2020 16:31:50
	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: 10 Jun 2021 08:15:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:31:51
User entered 'Not Related (NOT RELATED)'	Mikayla Frye (b) (4)	27 Oct 2020 16:45:29
	(b) (4)	

US3552371

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:53

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	23 Nov 2020 20:18:56
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 20:18:56
	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	Stanley Doublin (b) (4)	23 Nov 2020 17:56:49
DataPoint Verified.	(b) (4)	09 Nov 2020 16:31:53
	(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)	27 Oct 2020 16:45:29

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:53

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:31:55
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: 10 Jun 2021 08:15:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:31:56
User entered 'l'	Mikayla Frye (b) (4)	27 Oct 2020 16:45:29
	(b) (4)	

US3552371

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:31:58
User entered '0'	Mikayla Frye (b) (4)	27 Oct 2020 16:45:29

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:53

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:31:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Stanley Dublin (b) (4)	03 Nov 2020 16:27:05
Data Entry Error	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	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: 10 Jun 2021 08:15:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:32:01
User entered empty.	Mikayla Frye (b) (4)	27 Oct 2020 16:45:29
	(b) (4)	

US3552371

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:53

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	09 Nov 2020 16:32:03
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:32:03
	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: 10 Jun 2021 08:15:53

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09
User entered '0'	System	27 Oct 2020 16:45:29

US3552371

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:53

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09
User entered 'I'	System	27 Oct 2020 16:45:29

US3552371

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:15:53

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 04:03:57
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	09 Sep 2020 20:35:30
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:15:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	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)	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)	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)	09 Sep 2020 20:36:12

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:15:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:26
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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: 10 Jun 2021 08:15:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered 'hyperlipidemia'	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	Stanley Doublin (b) (4)	09 Sep 2020 20:36:12
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:15:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:26
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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: 10 Jun 2021 08:15:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:26
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:15:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	Stanley Doublin (b) (4)	09 Sep 2020 20:36:12
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:15:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered 'once daily (QD)'	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	Stanley Doublin (b) (4)	09 Sep 2020 20:36:12
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:15:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:26
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	Stanley Doublin (b) (4)	09 Sep 2020 20:36:12
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:15:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	Stanley Doublin (b) (4)	09 Sep 2020 20:36:12
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:15:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered 'un Oct 2018'	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	Stanley Doublin (b) (4)	09 Sep 2020 20:36:12
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:15:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered '0'	Stanley Dublin (b) (4)	09 Sep 2020 20:36:12
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:15:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:15:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:15:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	Stanley Doublin (b) (4)	09 Sep 2020 20:36:12
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:15:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:26
User entered 'I'	System	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: 10 Jun 2021 08:15:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:26
User entered 'I'	System	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: 10 Jun 2021 08:15:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:26
User entered '804 (804)'	System	09 Sep 2020 20:36:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:15:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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)	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)	09 Sep 2020 20:38:53
Data point term sent to Coder	System	09 Sep 2020 20:37:52
User entered 'levothyroxine'	Stanley Dublin (b) (4)	09 Sep 2020 20:37:13
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:15:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'No (N)'	Stanley Dublin (b) (4)	09 Sep 2020 20:37:13
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:15:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'hypothyroid'	Stanley Doublin (b) (4)	09 Sep 2020 20:37:13
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:15:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User closed query 'Per DM CLR: Previous response indicate data was updated; however, the dose recorded is still not the standard dose for this medication. Please correct the dosage or provide comment for alternate dosage. ' (Site from DM). Query 'Per DM CLR: Previous response indicate data was updated; however, the dose recorded is still not the standard dose for this medication. Please correct the dosage or provide comment for alternate dosage. ' answered with 'data is self reported by subject; per subject, this is the medication dose' (Site from DM). User opened query 'Per DM CLR: Previous response indicate data was updated; however, the dose recorded is still not the standard dose for this medication. Please correct the dosage or provide comment for alternate dosage. ' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6) Heather Douds (b) (4) (b) (4) (b) (4), (b) (6)	28 Jan 2021 06:50:29 25 Jan 2021 21:16:28 21 Jan 2021 04:55:48 15 Oct 2020 19:52:40 12 Oct 2020 08:54:33
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). 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). 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). User entered '.88'	Cassandra Zehenny (b) (4) (b) (4) (b) (4), (b) (6) Stanley Dublin (b) (4) (b) (4)	08 Oct 2020 21:41:58 08 Oct 2020 14:19:34 09 Sep 2020 20:37:13

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:15:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 15:36:13
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	19 Nov 2020 15:35:54
	(b) (4)	
User entered 'ug (ug)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	19 Nov 2020 15:35:54
	(b) (4)	
DataPoint Verified.	(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)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:15:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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).		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)	
	Cassandra Zehenny (b) (4)	19 Nov 2020 15:35:54
User entered empty; reason for change Data Entry Error	(b) (4)	
	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.	(b) (4)	
	Stanley Doublin (b) (4)	09 Sep 2020 20:37:13
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:15:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'once daily (QD)'	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: 10 Jun 2021 08:15:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'Oral (ORAL)'	Stanley Dublin (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: 10 Jun 2021 08:15:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'un May 1995'	Stanley Dublin (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: 10 Jun 2021 08:15:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered '0'	Stanley Dublin (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: 10 Jun 2021 08:15:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'Yes (Y)'	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: 10 Jun 2021 08:15:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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)	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)	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)	09 Sep 2020 20:38:08
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:15:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 15:36:13
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:06:16
	(b) (4)	
User entered 'Yes (Y)' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	11 Nov 2020 17:06:16
	(b) (4)	
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: 10 Jun 2021 08:15:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'health promotion'	Stanley Dublin (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: 10 Jun 2021 08:15:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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.		13 Oct 2020 10:34:27
' (Site from DM).		
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.	Cassandra Zehenny (b) (4)	08 Oct 2020 21:42:16
' answered with 'Subject reported data, exact dosage unknown. Thank you.' (Site from DM).	(b) (4)	
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.	(b) (4), (b) (6)	08 Oct 2020 14:19:43
' (Site from DM).		
User entered 'I'	Stanley Dublin (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: 10 Jun 2021 08:15:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'Oral (ORAL)'	Stanley Dublin (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: 10 Jun 2021 08:15:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'un Sep 2017'	Stanley Dublin (b) (4) (b) (4)	09 Sep 2020 20:38:08

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:15:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered '0'	Stanley Dublin (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: 10 Jun 2021 08:15:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'Yes (Y)'	Stanley Dublin (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: 10 Jun 2021 08:15:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	09 Sep 2020 20:38:08

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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)	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)	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)	09 Sep 2020 20:38:59
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:15:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 15:36:13
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:06:22
	(b) (4)	
User entered 'Yes (Y)' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	11 Nov 2020 17:06:22
	(b) (4)	
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: 10 Jun 2021 08:15:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'health promotion'	Stanley Dublin (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: 10 Jun 2021 08:15:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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.		13 Oct 2020 10:34:32
' (Site from DM).		
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.	Cassandra Zehenny (b) (4)	08 Oct 2020 21:42:21
' answered with 'Subject reported data, exact dosage unknown. Thank you.' (Site from DM).	(b) (4)	
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.	(b) (4), (b) (6)	08 Oct 2020 14:19:56
' (Site from DM).		
User entered 'I'	Stanley Dublin (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: 10 Jun 2021 08:15:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'tablet (TABLET)'	Stanley Dublin (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: 10 Jun 2021 08:15:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'once daily (QD)'	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: 10 Jun 2021 08:15:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'Oral (ORAL)'	Stanley Dublin (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: 10 Jun 2021 08:15:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'un Sep 2017'	Stanley Dublin (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: 10 Jun 2021 08:15:53

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered '0'	Stanley Dublin (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: 10 Jun 2021 08:15:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	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: 10 Jun 2021 08:15:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	09 Sep 2020 20:38:59

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:15:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Sep 2020 20:38:59

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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)	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)	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)	09 Sep 2020 20:39:37
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:15:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 15:36:13
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:06:38
	(b) (4)	
User entered 'Yes (Y)' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	11 Nov 2020 17:06:38
	(b) (4)	
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: 10 Jun 2021 08:15:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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.		13 Oct 2020 10:34:37
' (Site from DM).		
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.	Cassandra Zehenny (b) (4)	08 Oct 2020 21:42:25
' answered with 'Subject reported data, exact dosage unknown. Thank you.' (Site from DM).	(b) (4)	
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.	(b) (4), (b) (6)	08 Oct 2020 14:20:06
' (Site from DM).		
User entered 'I'	Stanley Dublin (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: 10 Jun 2021 08:15:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'tablet (TABLET)'	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: 10 Jun 2021 08:15:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'once daily (QD)'	Stanley Dublin (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: 10 Jun 2021 08:15:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'Oral (ORAL)'	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: 10 Jun 2021 08:15:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'un Sep 2017'	Stanley Dublin (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: 10 Jun 2021 08:15:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered '0'	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: 10 Jun 2021 08:15:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'Yes (Y)'	Stanley Dublin (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: 10 Jun 2021 08:15:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	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: 10 Jun 2021 08:15:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'No (N)'	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: 10 Jun 2021 08:15:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	09 Sep 2020 20:39:37

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	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)	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)	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)	09 Sep 2020 20:40:13

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:15:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:40
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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: 10 Jun 2021 08:15:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:40
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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) (b) (4)	09 Sep 2020 21:22:48
User entered 'health promotion'	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: 10 Jun 2021 08:15:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:40
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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).		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 Dublin (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: 10 Jun 2021 08:15:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:40
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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: 10 Jun 2021 08:15:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	Stanley Doublin (b) (4)	09 Sep 2020 20:40:13
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:15:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered 'as needed (PRN)'	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	Stanley Doublin (b) (4)	09 Sep 2020 20:40:13
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:15:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	Stanley Doublin (b) (4)	09 Sep 2020 20:40:13
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:15:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:40
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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: 10 Jun 2021 08:15:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	Stanley Doublin (b) (4)	09 Sep 2020 20:40:13
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:15:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered 'un UNK 1995'	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	Stanley Doublin (b) (4)	09 Sep 2020 20:40:13
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:15:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:40
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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: 10 Jun 2021 08:15:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'No (N)'	Stanley Doublin (b) (4)	09 Sep 2020 20:40:13
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:15:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered '05 Sep 2020'	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	Stanley Doublin (b) (4)	09 Sep 2020 20:40:13
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:15:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	Stanley Doublin (b) (4)	09 Sep 2020 20:40:13
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:15:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:40
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: 10 Jun 2021 08:15:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:40
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: 10 Jun 2021 08:15:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:40
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: 10 Jun 2021 08:15:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:54
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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: 10 Jun 2021 08:15:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	Stanley Doublin (b) (4)	29 Sep 2020 16:47:51
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:15:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:54
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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: 10 Jun 2021 08:15:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:54
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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: 10 Jun 2021 08:15:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	Stanley Doublin (b) (4)	29 Sep 2020 16:47:51
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:15:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	Stanley Doublin (b) (4)	29 Sep 2020 16:47:51
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:15:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered 'as needed (PRN)'	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	Stanley Doublin (b) (4)	29 Sep 2020 16:47:51
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:15:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:54
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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: 10 Jun 2021 08:15:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:54
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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: 10 Jun 2021 08:15:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	Stanley Doublin (b) (4)	29 Sep 2020 16:47:51
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:15:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:54
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered '16 Sep 2020'	Stanley Dublin (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: 10 Jun 2021 08:15:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	Stanley Doublin (b) (4)	29 Sep 2020 16:47:51
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:15:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:54
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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: 10 Jun 2021 08:15:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered '21 Sep 2020'	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	Stanley Doublin (b) (4)	29 Sep 2020 16:47:51
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:15:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:54
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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: 10 Jun 2021 08:15:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:54
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: 10 Jun 2021 08:15:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:54
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: 10 Jun 2021 08:15:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:54
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: 10 Jun 2021 08:15:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	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)	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)	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)	29 Sep 2020 16:53:29

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:15:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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: 10 Jun 2021 08:15:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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: 10 Jun 2021 08:15:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered '100'	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	Stanley Doublin (b) (4)	29 Sep 2020 16:53:29
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:15:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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: 10 Jun 2021 08:15:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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: 10 Jun 2021 08:15:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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: 10 Jun 2021 08:15:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	Stanley Doublin (b) (4)	29 Sep 2020 16:53:29
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:15:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	Stanley Doublin (b) (4)	29 Sep 2020 16:53:29
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:15:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	Stanley Dublin (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: 10 Jun 2021 08:15:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered '16 Sep 2020'	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	Stanley Dublin (b) (4)	29 Sep 2020 16:53:29
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:15:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	Stanley Doublin (b) (4)	29 Sep 2020 16:53:29
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:15:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	Stanley Doublin (b) (4)	29 Sep 2020 16:53:29
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:15:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered '21 Sep 2020'	Stanley Doublin (b) (4)	29 Sep 2020 16:53:29

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:15:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:22
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	Stanley Doublin (b) (4)	29 Sep 2020 16:53:29
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:15:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:22
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: 10 Jun 2021 08:15:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:22
User entered 'I'	System	29 Sep 2020 16:53:29

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:15:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:22
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: 10 Jun 2021 08:15:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	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)	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)	29 Sep 2020 22:57:44
Data point term sent to Coder	System	29 Sep 2020 16:54:41
User entered 'calcium supplement'	Stanley Dublin (b) (4)	29 Sep 2020 16:54:24

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:15:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 15:36:13
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:06:57
	(b) (4)	
User entered 'Yes (Y)' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	11 Nov 2020 17:06:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered 'No (N)'	Stanley Dublin (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: 10 Jun 2021 08:15:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered 'health'	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	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: 10 Jun 2021 08:15:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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: 10 Jun 2021 08:15:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 01 Feb 2021 21:51:27
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).		02 Dec 2020 04:56:13
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	(b) (4) 30 Nov 2020 18:59:07
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	(b) (4) 30 Nov 2020 18:58:44
User entered 'mg (mg)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	(b) (4) 30 Nov 2020 18:58:44
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 07:11:46
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: 10 Jun 2021 08:15:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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: 10 Jun 2021 08:15:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered 'once daily (QD)'	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	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: 10 Jun 2021 08:15:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:52:40
User entered empty.	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: 10 Jun 2021 08:15:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	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: 10 Jun 2021 08:15:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:00
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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: 10 Jun 2021 08:15:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered 'un UNK 2018'	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	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: 10 Jun 2021 08:15:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	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: 10 Jun 2021 08:15:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	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: 10 Jun 2021 08:15:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered '21 Sep 2020'	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	Stanley Dublin (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: 10 Jun 2021 08:15:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:00
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	15 Oct 2020 19:52:40
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 19:52:40
	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: 10 Jun 2021 08:15:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:00
User entered 'I'	System	29 Sep 2020 16:54:24

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:15:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:00
User entered 'I'	System	29 Sep 2020 16:54:24

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:15:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:00
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: 10 Jun 2021 08:15:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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) (b) (4)	08 Dec 2020 17:03:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Dec 2020 17:03:51
Data point term sent to Coder Coding entries removed.	System Stanley Doublin (b) (4) (b) (4)	08 Dec 2020 17:02:49 08 Dec 2020 17:02:28
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) (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.	Coder Import (b) (4) (b) (4)	27 Oct 2020 15:21:43
Data point term sent to Coder User entered 'influenza vaccine'	System Stanley Doublin (b) (4) (b) (4)	27 Oct 2020 15:21:12 27 Oct 2020 15:20:42

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:15:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	28 Oct 2020 21:05:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 21:05:09
	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: 10 Jun 2021 08:15:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	31 Jan 2021 04:08:38
DataPoint Un-verified.	(b) (4), (b) (6)	31 Jan 2021 04:08:38
DataPoint Un-verified.	Stanley Doublin (b) (4)	08 Dec 2020 17:02:28
User entered 'influenza PROPHYLAXIS' reason for change: Data Entry Error	(b) (4)	08 Dec 2020 17:02:28
DataPoint Verified.	Stanley Doublin (b) (4)	08 Dec 2020 17:02:28
DataPoint Verified.	(b) (4)	28 Oct 2020 21:05:11
User entered 'prophylaxis'	(b) (4), (b) (6)	28 Oct 2020 21:05:11
	Stanley Doublin (b) (4)	27 Oct 2020 15:20:42
	(b) (4)	27 Oct 2020 15:20:42

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:15:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:41:44
User entered 'l'	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: 10 Jun 2021 08:15:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	09 Nov 2020 16:41:45
User entered 'Other (OTHER)'	(b) (4), (b) (6)	09 Nov 2020 16:41:45
	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: 10 Jun 2021 08:15:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	09 Nov 2020 16:41:47
User entered 'injection'	(b) (4), (b) (6)	09 Nov 2020 16:41:47
	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: 10 Jun 2021 08:15:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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: 10 Jun 2021 08:15:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	09 Nov 2020 16:43:19
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:43:19
	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: 10 Jun 2021 08:15:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	09 Nov 2020 16:43:21
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	09 Nov 2020 16:43:21
	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: 10 Jun 2021 08:15:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	09 Nov 2020 16:43:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:43:23
	Stanley Dublin (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: 10 Jun 2021 08:15:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:31
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:05:12
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: 10 Jun 2021 08:15:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	09 Nov 2020 16:43:25
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 16:43:25
	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: 10 Jun 2021 08:15:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	09 Nov 2020 16:43:27
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 16:43:27
	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: 10 Jun 2021 08:15:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	09 Nov 2020 16:43:30
User entered '22 Oct 2020'	(b) (4), (b) (6)	09 Nov 2020 16:43:30
	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: 10 Jun 2021 08:15:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	09 Nov 2020 16:43:32
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 16:43:32
	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: 10 Jun 2021 08:15:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:31
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: 10 Jun 2021 08:15:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:31
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: 10 Jun 2021 08:15:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:31
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: 10 Jun 2021 08:15:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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) (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) (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) (b) (4)	27 Oct 2020 15:21:26

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:15:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:44:09
User entered 'No (N)'	Stanley Dublin (b) (4)	27 Oct 2020 15:21:26
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:15:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:44:11
User entered 'anxiety'	Stanley Dublin (b) (4)	27 Oct 2020 15:21:26
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:15:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:44:12
User entered '10'	Stanley Dublin (b) (4)	27 Oct 2020 15:21:26
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:15:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:44:14
User entered 'mg (mg)'	Stanley Doublin (b) (4)	27 Oct 2020 15:21:26
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:15:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:44:16
User entered empty.	Stanley Dublin (b) (4)	27 Oct 2020 15:21:26
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:15:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:44:19
User entered empty.	Stanley Dublin (b) (4)	27 Oct 2020 15:21:26
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:15:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:44:21
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4)	27 Oct 2020 15:21:26
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:15:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:44:24
User entered '22 Oct 2020'	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: 10 Jun 2021 08:15:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 16:44:26
User entered '0'	Stanley Doublin (b) (4)	27 Oct 2020 15:21:26
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:15:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM). Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'medication ongoing' (Site from DM). User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6) Cassandra Zehenny (b) (4) (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	25 Jan 2021 10:04:51 22 Jan 2021 22:15:21 21 Jan 2021 04:57:12 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) (b) (4)	27 Oct 2020 15:21:26

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:15:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:15:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:44:30
User entered 'No (N)'	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: 10 Jun 2021 08:15:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	27 Oct 2020 15:21:26

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:15:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Oct 2020 15:21:26

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:15:53

[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: 10 Jun 2021 08:15:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:48
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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)	29 Jan 2021 10:07:15
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 Jan 2021 10:07:15
Data point term sent to Coder	System	28 Jan 2021 20:22:24
Coding entries removed.	Cassandra Zehenny (b) (4) (b) (4)	28 Jan 2021 20:22:13
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: 10 Jun 2021 08:15:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	23 Nov 2020 15:36:13
User entered 'No (N)'	(b) (4), (b) (6)	23 Nov 2020 15:36:13
	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: 10 Jun 2021 08:15:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:48
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
User closed query 'Per DM CLR: Please note that there is no AE matching Con Med # 12 and # 14 indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 05:02:25
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:51:59
Query 'Per DM CLR: Please note that there is no AE matching Con Med # 12 and # 14 indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	28 Jan 2021 20:22:17
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	28 Jan 2021 20:22:13
User entered 'PARTIAL NEPHRECTOMY' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	28 Jan 2021 20:22:13
User opened query 'Per DM CLR: Please note that there is no AE matching Con Med # 12 and # 14 indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 03:31:09
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: 10 Jun 2021 08:15:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:48
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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: 10 Jun 2021 08:15:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:48
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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: 10 Jun 2021 08:15:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:48
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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: 10 Jun 2021 08:15:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:15:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:15:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	23 Nov 2020 15:36:13
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Nov 2020 15:36:13
	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: 10 Jun 2021 08:15:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	23 Nov 2020 15:36:13
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
	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: 10 Jun 2021 08:15:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	23 Nov 2020 15:36:13
User entered '13 Nov 2020'	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: 10 Jun 2021 08:15:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered '0'	Cassandra Zehenny (b) (4)	20 Nov 2020 17:51:53
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:15:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	21 Dec 2020 20:58:16
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 20:58:16
DataPoint Un-verified.	Stanley Doublin (b) (4)	08 Dec 2020 17:01:50
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	08 Dec 2020 17:01:50
DataPoint Verified.	Stanley Doublin (b) (4)	08 Dec 2020 17:01:50
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).	(b) (4)	20 Nov 2020 17:51:59
User entered empty.	System	20 Nov 2020 17:51:53
	Cassandra Zehenny (b) (4)	20 Nov 2020 17:51:53
	(b) (4)	20 Nov 2020 17:51:53

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:15:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	21 Dec 2020 20:58:17
DataPoint Un-verified.	(b) (4), (b) (6)	21 Dec 2020 20:58:17
DataPoint Un-verified.	Stanley Doublin (b) (4)	08 Dec 2020 17:01:50
User entered '17 Nov 2020' reason for change: Data Entry Error	(b) (4)	08 Dec 2020 17:01:50
DataPoint Verified.	Stanley Doublin (b) (4)	08 Dec 2020 17:01:50
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered empty.	(b) (4)	23 Nov 2020 15:36:13
	Cassandra Zehenny (b) (4)	20 Nov 2020 17:51:53
	(b) (4)	20 Nov 2020 17:51:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:15:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	23 Nov 2020 15:36:13
User entered 'No (N)'	(b) (4), (b) (6)	23 Nov 2020 15:36:13
	Cassandra Zehenny (b) (4)	20 Nov 2020 17:51:53
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:15:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:48
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: 10 Jun 2021 08:15:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:48
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: 10 Jun 2021 08:15:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:48
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: 10 Jun 2021 08:15:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:11
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: ELECTROLYTES NOS, PRODUCTSYNONYM: ELECTROLYTE SOLUTIONS [ELECTROLYTES NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Jan 2021 12:58:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Jan 2021 12:58:57
Data point term sent to Coder	System	22 Jan 2021 22:16:10
Coding entries removed.	Cassandra Zehenny (b) (4) (b) (4)	22 Jan 2021 22:15:43
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:57:37
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, PRODUCT: I.V. SOLUTIONS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 14:47:31
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 Dec 2020 14:47:31
Data point term sent to Coder	System	29 Dec 2020 22:49:50
User closed query 'For coding purposes, if ingredients are unknown please add (INGREDIENTS UNKNOWN) after the reported medication to enable coding' (Site from System).	System	29 Dec 2020 22:49:24
Query 'For coding purposes, if ingredients are unknown please add (INGREDIENTS UNKNOWN) after the reported medication to enable coding' answered with 'added' (Site from System).	Cassandra Zehenny (b) (4) (b) (4)	29 Dec 2020 22:49:24
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	29 Dec 2020 22:49:19

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:15:53

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'CRYSTALLOID FLUIDS [ingredients unknown]' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	29 Dec 2020 22:49:19
User opened query 'For coding purposes, if ingredients are unknown please add (INGREDIENTS UNKNOWN) after the reported medication to enable coding' (Site from System).	Coder Import (b) (4)	29 Dec 2020 15:28:26
Data point term sent to Coder	System	30 Nov 2020 19:00:24
User closed 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).	System	30 Nov 2020 18:59:21
Query 'CDM-Coding: Please update the term to include the active ingredient name(s) in brackets next to the drug to enable coding.' answered with 'unknown data' (Site from System).	Cassandra Zehenny (b) (4)	30 Nov 2020 18:59:21
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

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:15:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered 'No (N)'	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: 10 Jun 2021 08:15:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	31 Jan 2021 04:09:23
User closed query 'Per source indication - partial nephrectomy . Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	31 Jan 2021 04:09:21
Query 'Per source indication - partial nephrectomy . Please reconcile. ' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4)	22 Jan 2021 22:15:47
DataPoint Un-verified.	(b) (4)	22 Jan 2021 22:15:43
User entered 'partial nephrectomy' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	22 Jan 2021 22:15:43
User opened query 'Per source indication - partial nephrectomy . Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 20:57:30
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	23 Nov 2020 15:36:13
User entered '2500'	(b) (4), (b) (6)	23 Nov 2020 15:36:13
	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: 10 Jun 2021 08:15:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered 'other (OTHER)'	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: 10 Jun 2021 08:15:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered 'continuous'	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: 10 Jun 2021 08:15:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered 'Intravenous (INTRAVENOUS)'	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: 10 Jun 2021 08:15:53

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered '0'	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: 10 Jun 2021 08:15:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered 'No (N)'	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: 10 Jun 2021 08:15:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
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

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:15:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:11
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: 10 Jun 2021 08:15:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:11
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: 10 Jun 2021 08:15:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:11
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: 10 Jun 2021 08:15:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:39
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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: 10 Jun 2021 08:15:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered 'No (N)'	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: 10 Jun 2021 08:15:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered 'partial nephrectomy pain'	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: 10 Jun 2021 08:15:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered '30/3'	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: 10 Jun 2021 08:15:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered 'Other (OTHER)'	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: 10 Jun 2021 08:15:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:15:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	23 Nov 2020 15:36:13
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
	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: 10 Jun 2021 08:15:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered 'Intravenous (INTRAVENOUS)'	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: 10 Jun 2021 08:15:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:39
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	20 Nov 2020 17:56:40

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:15:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:15:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:39
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	20 Nov 2020 17:56:40

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:15:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered 'No (N)'	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: 10 Jun 2021 08:15:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:15:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 15:36:13
User entered 'No (N)'	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: 10 Jun 2021 08:15:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:39
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: 10 Jun 2021 08:15:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:39
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: 10 Jun 2021 08:15:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:40:39
User entered empty.	System	20 Nov 2020 17:56:40

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	21 Jan 2021 20:58:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Jan 2021 19:34:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Jan 2021 19:34:57
Data point term sent to Coder	System	12 Jan 2021 19:18:46
Coding entries removed.	Cassandra Zehenny (b) (4)	12 Jan 2021 19:18:20
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Jan 2021 14:58:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Jan 2021 14:58:55
Data point term sent to Coder	System	12 Jan 2021 13:08:39
User entered 'amoxicillin'	Stanley Doublin (b) (4)	12 Jan 2021 13:08:25

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:48
DataPoint Verified.	(b) (4)	18 Mar 2021 17:07:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 02:42:20
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	16 Feb 2021 16:43:32
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	16 Feb 2021 16:43:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	16 Feb 2021 16:43:07
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 05:19:36
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:58:07
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	12 Jan 2021 13:08:25

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:48
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
User closed query 'did subject had dental procedure done? Please update procedure eCRF as applicable. Please consider updating indication to " Dental procedure" as applicable. ' (Site from CRA).	(b) (4), (b) (6)	31 Jan 2021 04:09:51
Query 'did subject had dental procedure done? Please update procedure eCRF as applicable. Please consider updating indication to " Dental procedure" as applicable. ' answered with 'The true indication is prophylaxis, as is listed in indication; data correct as entered' (Site from CRA).	Heather Douds (b) (4) (b) (4)	25 Jan 2021 21:17:08
User opened query 'did subject had dental procedure done? Please update procedure eCRF as applicable. Please consider updating indication to " Dental procedure" as applicable. ' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 21:00:09
DataPoint Verified.		21 Jan 2021 20:58:07
User entered 'DENTAL PROCEDURE PROPHYLAXIS' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	12 Jan 2021 19:18:20
User entered 'preventative prophylaxis dental procedure'	Stanley Dublin (b) (4) (b) (4)	12 Jan 2021 13:08:25

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	21 Jan 2021 20:58:07
User entered '2000'	(b) (4), (b) (6)	21 Jan 2021 20:58:07
	Stanley Doublin (b) (4)	12 Jan 2021 13:08:25
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:48
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:58:07
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	12 Jan 2021 13:08:25

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:48
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:58:07
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Jan 2021 13:08:25

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	21 Jan 2021 20:58:07
User entered 'once (ONCE)'	(b) (4), (b) (6)	21 Jan 2021 20:58:07
	Stanley Doublin (b) (4)	12 Jan 2021 13:08:25
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	21 Jan 2021 20:58:07
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 20:58:07
	Stanley Doublin (b) (4)	12 Jan 2021 13:08:25
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	21 Jan 2021 20:58:07
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4)	12 Jan 2021 13:08:25
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	21 Jan 2021 20:58:07
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 20:58:07
	Stanley Doublin (b) (4)	12 Jan 2021 13:08:25
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	21 Jan 2021 20:58:07
User entered '11 Jan 2021'	(b) (4), (b) (6)	21 Jan 2021 20:58:07
	Stanley Dublin (b) (4)	12 Jan 2021 13:08:25
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:48
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:58:07
User entered '0'	Stanley Doublin (b) (4) (b) (4)	12 Jan 2021 13:08:25

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	21 Jan 2021 20:58:07
User entered 'No (N)'	(b) (4), (b) (6)	21 Jan 2021 20:58:07
	Stanley Doublin (b) (4)	12 Jan 2021 13:08:25
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	21 Jan 2021 20:58:07
User entered '11 Jan 2021'	(b) (4), (b) (6)	21 Jan 2021 20:58:07
	Stanley Doublin (b) (4)	12 Jan 2021 13:08:25
	(b) (4)	

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:48
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:58:07
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	12 Jan 2021 13:08:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:48
User entered empty.	System	12 Jan 2021 13:08:25

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:48
User entered empty.	System	12 Jan 2021 13:08:25

US3552371

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:39:48
User entered empty.	System	12 Jan 2021 13:08:25

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:15:53

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:33
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	04 Nov 2020 18:54:08
User entered 'Yes (Y)'	Joan Siegner (b) (4)	30 Oct 2020 16:03:24

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:15:53

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 15:38:01
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	20 Nov 2020 17:34:09
	(b) (4)	
User entered '08 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	20 Nov 2020 17:34:09
	(b) (4)	
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

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:15:53

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:52
User entered 'abdominal ultrasound'	Joan Siegner (b) (4)	30 Oct 2020 16:03:45

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:15:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:15:53

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:55
User entered empty.	Joan Siegner (b) (4)	30 Oct 2020 16:03:45

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:15:53

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	23 Nov 2020 15:38:11
User entered '12 Nov 2020'	Cassandra Zehenny (b) (4)	20 Nov 2020 17:34:30

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:15:53

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	23 Nov 2020 15:38:12
User entered 'Partial nephrectomy of right kidney'	(b) (4), (b) (6)	23 Nov 2020 15:38:12
	Cassandra Zehenny (b) (4)	20 Nov 2020 17:34:30
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:15:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:15:53

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:02
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	
	(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: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:15:53

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:46:54
User entered '11 Jan 2021'	Heather Douds (b) (4)	25 Jan 2021 21:26:43

US3552371

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:15:53

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:06
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4)	02 Feb 2021 15:46:56
User entered 'Dental procedure'	(b) (4), (b) (6)	02 Feb 2021 15:46:56
	Heather Douds (b) (4)	25 Jan 2021 21:26:43
	(b) (4)	

US3552371

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:15:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:06
DataPoint Verified.		18 Mar 2021 17:07:10
User closed query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).		01 Mar 2021 07:42:30
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:30:18
Query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'updated' (Site from DM).	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 25 Feb 2021 22:01:12
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	(b) (4) 25 Feb 2021 22:01:08
Signature has been broken.	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 25 Feb 2021 22:01:08
User entered 'Other (OTHER)' reason for change: New Information	(b) (4) Cassandra Zehenny (b) (4)	(b) (4) 25 Feb 2021 22:01:08
User opened query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 09:58:31
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 15:46:57
User entered 'Adverse Event (AE)'	Heather Douds (b) (4)	25 Jan 2021 21:26:43

US3552371

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:15:53

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:31:06
DataPoint Verified.	(b) (4)	18 Mar 2021 17:07:10
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:30:18
DataPoint Un-verified.	(b) (4)	(b) (4)
	Cassandra Zehenny (b) (4)	25 Feb 2021 22:01:08
Signature has been broken.	(b) (4)	(b) (4)
	Cassandra Zehenny (b) (4)	25 Feb 2021 22:01:08
User entered 'routine dental cleaning' reason for change: New Information	(b) (4)	(b) (4)
User signature succeeded.	Cassandra Zehenny (b) (4)	25 Feb 2021 22:01:08
	(b) (4)	(b) (4)
DataPoint Verified.	sharon frey (b) (4)	21 Feb 2021 18:59:42
	(b) (4)	(b) (4)
	(b) (4), (b) (6)	02 Feb 2021 15:46:59
User entered empty.	(b) (4)	(b) (4)
	Heather Douds (b) (4)	25 Jan 2021 21:26:43
	(b) (4)	(b) (4)

US3552371

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:15:53

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:32:18
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:54:58
User entered '13 Oct 2020'	Cassandra Zehenny (b) (4) (b) (4)	15 Oct 2020 20:32:10

US3552371

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:15:53

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:32:18
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:59:42
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: 10 Jun 2021 08:15:53

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:32:18
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 18:59:42
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
		18 Nov 2020 20:14:16
Query 'Per CDM: Please record AE record number instead of details ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	18 Nov 2020 17:44:45
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	18 Nov 2020 17:44:42
User entered 'AE #2' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	18 Nov 2020 17:44:42
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
		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
User entered 'Elevated liver enzyme'	Cassandra Zehenny (b) (4)	15 Oct 2020 20:32:10

US3552371

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
Reviewed for Safety.	(b) (4)	20 Jan 2021 22:29:46
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 01:49:36
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.		23 Nov 2020 20:19:17
User closed query 'Please enter site's address information ' (Site from CRA).		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
User entered '1100 S. Grand Blvd'	(b) (4)	
	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: 10 Jun 2021 08:15:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
Reviewed for Safety.	(b) (4)	20 Jan 2021 22:29:46
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 01:49:37
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.		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: 10 Jun 2021 08:15:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:29:46
DataPoint Verified.		30 Nov 2020 01:49:39
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.		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: 10 Jun 2021 08:15:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.		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: 10 Jun 2021 08:15:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
User entered '4'	(b) (4) System	20 Jan 2021 22:29:59
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: 10 Jun 2021 08:15:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
Reviewed for Safety.	(b) (4)	20 Jan 2021 22:29:46
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 01:49:36
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.		23 Nov 2020 20:19:17
User closed query 'Please enter site's address information ' (Site from CRA).		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
User entered '1100 S. Grand Blvd'	(b) (4)	
	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: 10 Jun 2021 08:15:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:29:46
DataPoint Verified.		30 Nov 2020 01:49:37
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.		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: 10 Jun 2021 08:15:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:29:46
DataPoint Verified.		30 Nov 2020 01:49:39
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.		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: 10 Jun 2021 08:15:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
User entered '4'	(b) (4) System	20 Jan 2021 22:29:59
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: 10 Jun 2021 08:15:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	23 Nov 2020 15:35:20
User entered '20/Nov/2020 14:06'	(b) (4), (b) (6) System	20 Nov 2020 14:06:52

US3552371

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

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:15:53

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 signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	23 Nov 2020 15:35:20
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 14:49:12
User entered 'l'		20 Nov 2020 14:06:52

US3552371

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
Reviewed for Safety.	(b) (4)	20 Jan 2021 22:29:46
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 01:49:36
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.		23 Nov 2020 20:19:17
User closed query 'Please enter site's address information ' (Site from CRA).		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
User entered '1100 S. Grand Blvd'	(b) (4)	
	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: 10 Jun 2021 08:15:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
Reviewed for Safety.	(b) (4)	20 Jan 2021 22:29:46
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 01:49:37
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.		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: 10 Jun 2021 08:15:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.		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: 10 Jun 2021 08:15:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
Reviewed for Safety.	(b) (4)	20 Jan 2021 22:29:46
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 01:49:39
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.		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: 10 Jun 2021 08:15:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:35:20
Reviewed for Safety.		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: 10 Jun 2021 08:15:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
User entered '4'	(b) (4) System	20 Jan 2021 22:29:59
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: 10 Jun 2021 08:15:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:53

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 signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 12:46:11
DataPoint Verified.		23 Nov 2020 15:35:20
User entered 'l'		23 Nov 2020 14:49:26

US3552371

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:29:46
DataPoint Verified.		30 Nov 2020 01:49:36
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.		23 Nov 2020 20:19:17
User closed query 'Please enter site's address information ' (Site from CRA).		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
User entered '1100 S. Grand Blvd'	(b) (4)	
	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: 10 Jun 2021 08:15:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:29:46
DataPoint Verified.		30 Nov 2020 01:49:37
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.		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: 10 Jun 2021 08:15:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:53

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:29:46
DataPoint Verified.		30 Nov 2020 01:49:39
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.		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: 10 Jun 2021 08:15:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
User entered '4'	(b) (4) System	20 Jan 2021 22:29:59
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: 10 Jun 2021 08:15:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 01:49:47
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: 10 Jun 2021 08:15:53

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 signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
Reviewed for Safety.	(b) (4)	20 Jan 2021 22:29:46
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 01:49:49
User entered 'l'		24 Nov 2020 12:46:20

US3552371

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:15:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:15:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:29:46
DataPoint Verified.		30 Nov 2020 01:49:36
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.		23 Nov 2020 20:19:17
User closed query 'Please enter site's address information ' (Site from CRA).		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
User entered '1100 S. Grand Blvd'	(b) (4)	
	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: 10 Jun 2021 08:15:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:29:46
DataPoint Verified.		30 Nov 2020 01:49:37
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.		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: 10 Jun 2021 08:15:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:29:46
DataPoint Verified.		30 Nov 2020 01:49:39
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.		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: 10 Jun 2021 08:15:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 08:15:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
User entered '4'	(b) (4) System	20 Jan 2021 22:29:59
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 (4)

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[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:13:50
User entered '20/Jan/2021 22:29'	System	20 Jan 2021 22:29:59

US3552371

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

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:15:53

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 signature succeeded.	sharon frey (b) (4)	21 Feb 2021 19:00:03
DataPoint Verified.	(b) (4)	21 Jan 2021 21:13:52
User entered 'l'	(b) (4), (b) (6)	20 Jan 2021 22:29:59