

US3552331 (Prod: Saint Louis University)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:13:46

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US3552331

Form: Participant Creation

Data signed: (b) (4) 21 Feb 2021 18:49:17

Generated On: 10 Jun 2021 08:13:46

Participant ID

US3552331

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

US3552331

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:49:19

Generated On: 10 Jun 2021 08:13:46

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	04 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Date of Birth (MMM yyyy)	(b) (6) 1976
Age	44
Age Units	YEARS
Age (Derived)	44
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Date of Informed Consent (dd MMM yyyy) 04 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	☐
Amendment 2	☐
Amendment 3	☒
Amendment 4	☐
Amendment 5	☐

Was participant enrolled in the study?

Yes	☒
No	☐

If No, indicate reason for screen fail

Withdrew Consent	☐
Inclusion/Exclusion	☐
Cohort Full	☐
Other	☐

If reason for screen fail is Other, specify _____

Was this participant screened previously?

Yes	☐
No	☒

If Yes, previous participant number _____

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

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 18:49:18

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Condition	HEADACHE
Start date (dd MMM yyyy)	UN UNK 1996
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Condition	ECZEMA
Start date (dd MMM yyyy)	UN UNK 1981
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1981
Start Year (derived)	1981
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Condition	AUGMENTIN ALLERGY
Start date (dd MMM yyyy)	UN UNK 1989
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1989
Start Year (derived)	1989
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3552331

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Condition	OBESITY
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Condition	GASTRIC SLEEVE
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Condition	AIRPLANE FLIGHT ANXIETY
Start date (dd MMM yyyy)	UN UNK 2006
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	
Stop Year (derived)	

US3552331

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3552331

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 18:49:19

Generated On: 10 Jun 2021 08:13:46

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	04 SEP 2020
Time of assessment (00:00-23:59)	11:27 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 11:27
Height (xxx.x)	70 in
Weight (xxx.x)	199 lb
BMI (xxx.x)	28.61323 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
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 18:49:18

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 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 18:49:18

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Date of assessment (dd MMM yyyy) 04 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) _____

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (<i>dd MMM yyyy</i>)	04 SEP 2020
Test performed	Urine ☒
	Serum ☐
Result	Positive ☐
	Negative ☒
Was FSH sample collected?	Yes ☐
	No ☒
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 18:49:18

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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

TEENAGE CHILDREN
ATTENDING IN HOUSE SCHOOL

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 18:49:18

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	True
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:49:19

Generated On: 10 Jun 2021 08:13:46

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	04 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 21 Feb 2021 18:49:19

Generated On: 10 Jun 2021 08:13:46

What was the date of randomization? (dd MMM yyyy) 04 SEP 2020

What was the participant's randomization number? 111900

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 18:49:19

Generated On: 10 Jun 2021 08:13:46

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 18:49:19

Generated On: 10 Jun 2021 08:13:46

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	04 SEP 2020
Time of assessment (00:00-23:59)	11:27 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 11:27
Temperature (xxx.x)	98.4 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 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 18:49:19

Generated On: 10 Jun 2021 08:13:46

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	04 SEP 2020
Time of assessment (00:00-23:59)	13:06 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 13:06
Temperature (xxx.x)	98.3 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 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 18:49:19

Generated On: 10 Jun 2021 08:13:46

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.

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 21 Feb 2021 18:49:19

Generated On: 10 Jun 2021 08:13:46

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 18:49:19

Generated On: 10 Jun 2021 08:13:46

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) 04 SEP 2020

What was the treatment time? (00:00-23:59) 12:35 (24 HR)

Treatment Date and Time (derived) 04 SEP 2020 12:35

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 18:49:19

Generated On: 10 Jun 2021 08:13:46

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	04 SEP 2020
Collection time (00:00-23:59)	12:00 (24 HR)
Collection date and time (derived)	04 SEP 2020 12:00

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 18:49:19

Generated On: 10 Jun 2021 08:13:46

Collection date (dd MMM yyyy)			04 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:05	04 SEP 2020 12:05
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:49:19

Generated On: 10 Jun 2021 08:13:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 13:05

PC Open Date & Time

04 SEP 2020 12:55

PC Close Date & Time

04 SEP 2020 15:25

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:46

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 97.7 °F

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

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

PC Time Stamp	04 SEP 2020 20:23
PC Open Date & Time	04 SEP 2020 16:20
PC Close Date & Time	05 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 18:50

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

06 SEP 2020 18:33

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 20:56

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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 06:24

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 04:15

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:46

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

10 SEP 2020 23:32

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:46

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

04 SEP 2020 13:06

PC Open Date & Time

04 SEP 2020 12:55

PC Close Date & Time

04 SEP 2020 15:25

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:46

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

04 SEP 2020 20:24

PC Open Date & Time

04 SEP 2020 16:20

PC Close Date & Time

05 SEP 2020 11:59

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:46

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

05 SEP 2020 18:51

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:46

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

06 SEP 2020 18:33

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:46

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

07 SEP 2020 20:56

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:46

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

09 SEP 2020 06:24

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:46

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

10 SEP 2020 04:16

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:46

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

10 SEP 2020 23:32

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:46

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 13:06

PC Open Date & Time	04 SEP 2020 12:55

PC Close Date & Time	04 SEP 2020 15:25

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:46

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 20:25
PC Open Date & Time	04 SEP 2020 16:20
PC Close Date & Time	05 SEP 2020 11:59

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:46

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:46

Yes ☐	
PC Time stamp	05 SEP 2020 18:52
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:46

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

56 of 1984

EAB) (1725)

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:46

Yes ☐	
PC Time stamp	06 SEP 2020 18:34
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:46

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

58 of 1984

EAB) (1725)

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:46

Yes ☐	
PC Time stamp	07 SEP 2020 20:56
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:46

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

60 of 1984

EAB) (1725)

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:46

Yes ☐	
PC Time stamp	09 SEP 2020 06:24
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:46

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

62 of 1984

EAB) (1725)

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:46

Yes ☐	
PC Time stamp	10 SEP 2020 04:17
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:46

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

64 of 1984

EAB) (1725)

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:46

Yes ☐	
PC Time stamp	10 SEP 2020 23:32
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3552331

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552331

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552331

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552331

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552331

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552331

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552331

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:49:19

Generated On: 10 Jun 2021 08:13:46

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	01 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3552331

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 18:49:19

Generated On: 10 Jun 2021 08:13:46

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	01 OCT 2020
Time of assessment (00:00-23:59)	08:35 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 08:35
Temperature (xxx.x)	97.9 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3552331

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 18:49:19

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 18:49:19

Generated On: 10 Jun 2021 08:13:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 OCT 2020

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

US3552331

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 21 Feb 2021 18:49:19

Generated On: 10 Jun 2021 08:13:46

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (dd MMM yyyy)	01 OCT 2020
Test performed	Urine ☒
	Serum ☐
Result	Positive ☐
	Negative ☒
Was FSH sample collected?	Yes ☐
	No ☒
Collection date	
Collection time	
Collection date and time (derived)	

US3552331

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 18:49:19

Generated On: 10 Jun 2021 08:13:46

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

RECENT EPISODE OF WORSENING DEPRESSION

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? _____

US3552331

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 18:49:19

Generated On: 10 Jun 2021 08:13:46

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	01 OCT 2020
Collection time (00:00-23:59)	09:35 (24 HR)
Collection date and time (derived)	01 OCT 2020 09:35

US3552331

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 18:49:19

Generated On: 10 Jun 2021 08:13:46

Collection date (dd MMM yyyy)			01 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:36	01 OCT 2020 09:36
Nasopharyngeal Swab 2	No		

US3552331

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:49:19

Generated On: 10 Jun 2021 08:13:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552331

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552331

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552331

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552331

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552331

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552331

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552331

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:49:30

Generated On: 10 Jun 2021 08:13:46

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	29 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3552331

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 18:49:30

Generated On: 10 Jun 2021 08:13:46

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) _____

US3552331

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 18:49:30

Generated On: 10 Jun 2021 08:13:46

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.

US3552331

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 18:49:30

Generated On: 10 Jun 2021 08:13:46

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	29 OCT 2020
Collection time (00:00-23:59)	08:39 (24 HR)
Collection date and time (derived)	29 OCT 2020 08:39

US3552331

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:49:19

Generated On: 10 Jun 2021 08:13:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552331

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 NOV 2020 23:23:40
Patient Cloud Open Date & Time	04 NOV 2020 00:01
Patient Cloud Close Date & Time	08 NOV 2020 23:59

US3552331

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 06:03:08

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3552331

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 NOV 2020 05:45:42
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 06:59:41
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 NOV 2020 12:34:23
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 DEC 2020 06:05:52
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 DEC 2020 00:01:48

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 DEC 2020 16:29:47
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

27 DEC 2020 07:34:41

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 JAN 2021 06:56:03
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 14:53:35
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

17 JAN 2021 07:13:46

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

24 JAN 2021 06:10:51

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 08:12:54

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

08 FEB 2021 08:36:40

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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	14 FEB 2021 15:45:26
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

21 FEB 2021 06:11:15

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 FEB 2021 07:43:01
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

07 MAR 2021 16:43:07

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 MAR 2021 23:12:58
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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	21 MAR 2021 06:02:56
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

28 MAR 2021 17:55:11

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

04 APR 2021 10:39:00

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

11 APR 2021 06:36:40

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

18 APR 2021 01:09:39

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

25 APR 2021 00:05:57

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

Date and time of submission

02 MAY 2021 01:09:50

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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 JAN 2022 00:01

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20 JAN 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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°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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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 JAN 2022 00:01

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27 JAN 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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30 JAN 2022 00:01

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03 FEB 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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10 FEB 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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Date and time of submission

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US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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Date and time of submission

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US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

Date and time of submission

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10 MAR 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 MAR 2022 00:01
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US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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31 MAR 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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 APR 2022 00:01

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07 APR 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

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

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14 APR 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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 AUG 2022 00:01

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11 AUG 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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 AUG 2022 00:01

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25 AUG 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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 AUG 2022 00:01

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01 SEP 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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

Date and time of submission

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04 SEP 2022 00:01

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08 SEP 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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11 SEP 2022 00:01

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15 SEP 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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18 SEP 2022 00:01

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22 SEP 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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29 SEP 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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06 OCT 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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20 OCT 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

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

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3552331

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:13:46

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 07:43:17

US3552331

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552331

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552331

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552331

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552331

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552331

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552331

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 27 Feb 2021 17:55:45

Generated On: 10 Jun 2021 08:13:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552331

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 27 Feb 2021 17:55:45

Generated On: 10 Jun 2021 08:13:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552331

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 30 Mar 2021 16:30:28

Generated On: 10 Jun 2021 08:13:46

Was this visit performed?	Yes ☒
	No ☐

Visit date (dd MMM yyyy)	29 MAR 2021

Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒

Folder OID	VISIT4

US3552331

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Mar 2021 16:30:28

Generated On: 10 Jun 2021 08:13:46

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) _____

US3552331

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 30 Mar 2021 16:30:28

Generated On: 10 Jun 2021 08:13:46

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.

US3552331

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Mar 2021 16:30:28

Generated On: 10 Jun 2021 08:13:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 MAR 2021

Collection time (00:00-23:59)

08:13 (24 HR)

Collection date and time (derived)

29 MAR 2021 08:13

US3552331

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 16:30:28

Generated On: 10 Jun 2021 08:13:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552331

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3552331

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:13:46

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3552331

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

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	02 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	UNBLND_DECIDE

US3552331

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

Form: Unblinding

Data signed: (b) (4) 23 Mar 2021 15:36:42

Generated On: 10 Jun 2021 08:13:46

Date of updated informed consent (<i>dd MMM yyyy</i>)	02 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ☒ No ☐
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ☐ Amendment 6 or later ☒
Date of unblinding (<i>dd MMM yyyy</i>)	02 FEB 2021
Participant randomization assignment	mRNA-1273 ☐ Placebo ☒
Actual Dose 1	mRNA-1273 ☐ Placebo ☒ Not Administered ☐
Actual Dose 2	mRNA-1273 ☐ Placebo ☐ Not Administered ☒
Will participant receive mRNA-1273?	Yes ☒ No ☐
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3552331

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

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

US3552331

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	02 FEB 2021
Time of assessment (00:00-23:59)	08:34 (24 HR)
Vital Signs Date and Time (derived)	02 FEB 2021 08:34
Temperature (xxx.x)	98.1 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3552331

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	02 FEB 2021
Time of assessment (00:00-23:59)	09:38 (24 HR)
Vital Signs Date and Time (derived)	02 FEB 2021 09:38
Temperature (xxx.x)	98.5 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	99 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3552331

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

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 FEB 2021

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

US3552331

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

Form: Pregnancy Test

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (<i>dd MMM yyyy</i>)	02 FEB 2021
Test performed	Urine ☒
	Serum ☐
Result	Positive ☐
	Negative ☒
Was FSH sample collected?	Yes ☐
	No ☒
Collection date	
Collection time	
Collection date and time (derived)	

US3552331

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

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

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) 02 FEB 2021

What was the treatment time? (00:00-23:59) 09:08 (24 HR)

Treatment Date and Time (derived) 02 FEB 2021 09:08

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

US3552331

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	02 FEB 2021
Collection time (00:00-23:59)	08:22 (24 HR)
Collection date and time (derived)	02 FEB 2021 08:22

US3552331

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 21 Feb 2021 18:49:17

Generated On: 10 Jun 2021 08:13:46

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	02 FEB 2021
Collection time (00:00 - 23:59)	08:25
Collection Date and Time (derived)	02 FEB 2021 08:25

US3552331

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

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552331

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552331

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

OLD29 Placebo Flag

1

US3552331

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 16:59:35

Generated On: 10 Jun 2021 08:13:46

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	03 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	OLD29

US3552331

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Mar 2021 16:59:35

Generated On: 10 Jun 2021 08:13:46

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	03 MAR 2021
Time of assessment (00:00-23:59)	14:21 (24 HR)
Vital Signs Date and Time (derived)	03 MAR 2021 14:21
Temperature (xxx.x)	96.8 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3552331

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Mar 2021 16:59:35

Generated On: 10 Jun 2021 08:13:46

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	03 MAR 2021
Time of assessment (00:00-23:59)	15:16 (24 HR)
Vital Signs Date and Time (derived)	03 MAR 2021 15:16
Temperature (xxx.x)	97.2 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3552331

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 16:59:35

Generated On: 10 Jun 2021 08:13:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 MAR 2021

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

US3552331

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 09 Mar 2021 16:59:35

Generated On: 10 Jun 2021 08:13:46

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (<i>dd MMM yyyy</i>)	03 MAR 2021
Test performed	Urine ☒
	Serum ☐
Result	Positive ☐
	Negative ☒
Was FSH sample collected?	Yes ☐
	No ☒
Collection date	
Collection time	
Collection date and time (derived)	

US3552331

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 09 Mar 2021 16:59:35

Generated On: 10 Jun 2021 08:13:46

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) 03 MAR 2021

What was the treatment time? (00:00-23:59) 14:46 (24 HR)

Treatment Date and Time (derived) 03 MAR 2021 14:46

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

US3552331

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 16:59:35

Generated On: 10 Jun 2021 08:13:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552331

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Mar 2021 15:36:42

Generated On: 10 Jun 2021 08:13:46

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 MAR 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552331

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 15:36:42

Generated On: 10 Jun 2021 08:13:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552331

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 30 Mar 2021 16:30:28

Generated On: 10 Jun 2021 08:13:46

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	29 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	OLD57

US3552331

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Mar 2021 16:30:28

Generated On: 10 Jun 2021 08:13:46

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) _____

US3552331

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 30 Mar 2021 16:30:28

Generated On: 10 Jun 2021 08:13:46

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.

US3552331

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Mar 2021 16:30:27

Generated On: 10 Jun 2021 08:13:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 MAR 2021

Collection time (00:00-23:59)

08:13 (24 HR)

Collection date and time (derived)

29 MAR 2021 08:13

US3552331

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 21 Feb 2021 18:49:17

Generated On: 10 Jun 2021 08:13:46

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3552331

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 21 Feb 2021 18:49:17

Generated On: 10 Jun 2021 08:13:46

AEID	USA-US089-2020-MRNA-1273-P30 1000004
Adverse event	WORSENING DEPRESSION
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)	14 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)	01 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	21 SEP 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (1)

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

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 21 Feb 2021 18:49:17

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SUBJECT TOOK 5 TRAZADONE
IN ATTEMPT TO SLEEP AFTER
HAVING DIFFICULTIES WITH
HER DAUGHTER. WHEN HER
DAUGHTER HAD TROUBLE
AROUSING HER THE NEXT
MORNING, SHE CALLED 911
AND SUBJECT WAS ADMITTED
TO PSYCHIATRIC WARD OF
LOCAL HOSPITAL. REMAINS
HOSPITALIZED AT THIS TIME.
9/30/20 UPDATE: INPATIENT
RECORDS INDICATE THAT
SUBJECT WAS TREATED WITH
INDIVIDUAL PSYCHOTHERAPY,
GROUP THERAPY AND
INPATIENT MILIEU, PROVIDED
WITH MED EDUCATION AND
PSYCHOEDUCATION. SUBJECT
HAD A GOOD RESPONSE AND
THE CRISIS WHICH PROMPTED
THE ADMISSION WERE
"ADEQUATELY RESOLVED."

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

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 21 Feb 2021 18:49:17

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 21 Feb 2021 18:49:17

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Name of Medication GIANVI

Prophylaxis Yes ☒
No ☐

Indication BIRTH CONTROL

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 (1)

Data signed: (b) (4) 21 Feb 2021 18:49:17

Generated On: 10 Jun 2021 08:13:46

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JUN 2019	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 21 Feb 2021 18:49:17

Generated On: 10 Jun 2021 08:13:46

Name of Medication C GUMMIE VITAMIN [VITAMIN C]

Prophylaxis Yes ☒
No ☐

Indication HEALTH PROMOTION

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 21 Feb 2021 18:49:17

Generated On: 10 Jun 2021 08:13:46

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 JUN 2018
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 21 Feb 2021 18:49:17

Generated On: 10 Jun 2021 08:13:46

Name of Medication MULTIVITMAIN

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 18:49:17

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 JUN 2018
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 21 Feb 2021 18:49:17

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Name of Medication POTASSIUM

Prophylaxis Yes ☒
No ☐

Indication HEALTH PROMOTION

Dose per administration 99

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 18:49:17

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 JUN 2018
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 21 Feb 2021 18:49:17

Generated On: 10 Jun 2021 08:13:46

Name of Medication MAGNESIUM

Prophylaxis Yes ☒
No ☐

Indication HEALTH PROMOTION

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 21 Feb 2021 18:49:17

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 JUN 2018
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 21 Feb 2021 18:49:17

Generated On: 10 Jun 2021 08:13:46

Name of Medication EFFEXOR

Prophylaxis Yes ☐
No ☒

Indication WORSENING DEPRESSION

Dose per administration 75

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 18:49:17

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 21 Feb 2021 18:49:17

Generated On: 10 Jun 2021 08:13:46

Name of Medication LEXAPRO

Prophylaxis Yes ☐
No ☒

Indication WORSENING DEPRESSION

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 (7)

Data signed: (b) (4) 21 Feb 2021 18:49:17

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 21 Feb 2021 18:49:17

Generated On: 10 Jun 2021 08:13:46

Name of Medication TRAZODONE

Prophylaxis Yes ☐
No ☒

Indication WORSENING DEPRESSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 21 Feb 2021 18:49:17

Generated On: 10 Jun 2021 08:13:46

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

US3552331

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 21 Feb 2021 18:49:17

Generated On: 10 Jun 2021 08:13:46

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 21 Feb 2021 18:49:17

Generated On: 10 Jun 2021 08:13:46

Date of dosing discontinuation (dd MMM yyyy)	01 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	SAE #1

US3552331

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:13:46

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 ☐

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

SAEID	USA-US089-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	9

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

SAEID	USA-US089-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	9
Date of submission (Pre-filled from custom function)	22/SEP/2020 10:03
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

SAEID	USA-US089-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	9
Date of submission (Pre-filled from custom function)	29/SEP/2020 09:07
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

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

SAEID	USA-US089-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	9
Date of submission (Pre-filled from custom function)	02/OCT/2020 08:14
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

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

SAEID	USA-US089-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	9
Date of submission (Pre-filled from custom function)	09/OCT/2020 13:26
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

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

SAEID	USA-US089-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	9
Date of submission (Pre-filled from custom function)	13/OCT/2020 14:20
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

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

SAEID	USA-US089-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	9
Date of submission (Pre-filled from custom function)	19/OCT/2020 15:46
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

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

SAEID	USA-US089-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	9
Date of submission (Pre-filled from custom function)	27/OCT/2020 08:24
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

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form (8)

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

SAEID	USA-US089-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	9
Date of submission (Pre-filled from custom function)	10/NOV/2020 09:50
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

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form (9)

Data signed: (b) (4) 21 Feb 2021 18:49:18

Generated On: 10 Jun 2021 08:13:46

SAEID	USA-US089-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	9
Date of submission (Pre-filled from custom function)	29/JAN/2021 18:39
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

US3552331 (Prod: Saint Louis University)

US3552331

Form: Participant Creation

Generated On: 10 Jun 2021 08:13:46

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:49:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
User entered 'US3552331'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 16:39:42

US3552331

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:13:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:11:33
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:20:51

US3552331

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:11:33
User entered '04 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 16:39:43

US3552331

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:13:46

[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 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:11:33
User entered 'Clinic (Clinic)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:20:51

US3552331

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:13:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered 'SCRN'	System	04 Sep 2020 19:20:51

US3552331

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:46

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:11:41
User entered (b) (6) 1976'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 16:39:45

US3552331

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:46

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:11:41
User entered '44'	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:21:43

US3552331

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:46

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered 'YEARS'	System	04 Sep 2020 19:21:43

US3552331

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:46

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered '44'	System	04 Sep 2020 17:08:03

US3552331

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:46

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:11:41
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 19:21:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 19:21:55
User entered 'Female (F)' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:21:55
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 19:21:43
User entered empty.	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:21:43

US3552331

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:46

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:11:41
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:21:43

US3552331

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:46

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:11:41
User entered 'l'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:21:43

US3552331

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:46

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:11:41
User entered '0'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:21:43

US3552331

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:46

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:11:41
User entered '0'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:21:43

US3552331

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:46

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:11:41
User entered '0'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:21:43

US3552331

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:46

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:11:41
User entered '0'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:21:43

US3552331

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:11:41
User entered '0'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:21:43

US3552331

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:46

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:11:41
User entered empty.	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:21:43

US3552331

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:46

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:11:41
User entered '0'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:21:43

US3552331

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:46

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:11:41
User entered '0'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:21:43

US3552331

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:13:46

Date of Informed Consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	10 Nov 2020 20:34:24
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	09 Nov 2020 16:21:40
User entered '04 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 16:21:40
DataPoint Verified.	(b) (4)	30 Sep 2020 16:12:11
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 17:08:03

US3552331

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered 'Sep 2020'	System	04 Sep 2020 17:08:03

US3552331

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered '2020'	System	04 Sep 2020 17:08:03

US3552331

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:13:46

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	30 Sep 2020 16:12:11
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	04 Sep 2020 17:08:03

US3552331

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:12:11
User entered 'Yes (Y)'		04 Sep 2020 17:08:03

US3552331

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	30 Sep 2020 16:12:11
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 17:08:03

US3552331

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:13:46

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:12:11
User entered empty.		04 Sep 2020 17:08:03

US3552331

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:13:46

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:12:11
User entered 'No (N)'		04 Sep 2020 17:08:03

US3552331

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:13:46

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:12:11
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 16:39:43

US3552331

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:13:46

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered 'l'	System	04 Sep 2020 17:08:10

US3552331

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:12:18
User entered 'Yes (Y)'		04 Sep 2020 17:08:10

US3552331

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:13:46

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:12:23
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:22:03

US3552331

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:13:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:24:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:24:46
Data point term sent to Coder	System	04 Sep 2020 19:23:10
User entered 'headache'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:22:21

US3552331

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered 'un UNK 1996'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:22:21

US3552331

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:13:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered '0'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:22:21

US3552331

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:13:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:22:21

US3552331

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered empty.	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:22:21

US3552331

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:13:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered '0'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:22:21

US3552331

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered 'Jan 1996'	System	04 Sep 2020 19:22:21

US3552331

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered '1996'	System	04 Sep 2020 19:22:21

US3552331

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered empty.	System	04 Sep 2020 19:22:21

US3552331

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered empty.	System	04 Sep 2020 19:22:21

US3552331

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:13:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User coded data point as SOC: Reproductive system and breast disorders, HLG: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation with increased bleeding, PT: Menorrhagia, LLT: Menorrhagia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:25:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:25:48
Data point term sent to Coder	System	04 Sep 2020 19:24:11
User entered 'menorrhagia'	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:23:53

US3552331

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered 'un Jan 2018'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:23:53

US3552331

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:13:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered '0'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:23:53

US3552331

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:13:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:23:53

US3552331

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered 'un Jun 2019'	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:23:53

US3552331

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:13:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered '0'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:23:53

US3552331

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered 'Jan 2018'	System	04 Sep 2020 19:23:53

US3552331

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered '2018'	System	04 Sep 2020 19:23:53

US3552331

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered 'Jun 2019'	System	04 Sep 2020 19:23:53

US3552331

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered '2019'	System	04 Sep 2020 19:23:53

US3552331

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:13:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Endometrial ablation, LLT: Uterine ablation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:26:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:26:41
Data point term sent to Coder	System	04 Sep 2020 19:25:14
User entered 'uterine ablation'	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:24:21

US3552331

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered 'un Jun 2019'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:24:21

US3552331

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:13:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered '0'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:24:21

US3552331

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:13:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:24:21

US3552331

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered 'un Jun 2019'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:24:21

US3552331

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:13:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered '0'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:24:21

US3552331

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered 'Jun 2019'	System	04 Sep 2020 19:24:21

US3552331

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:13:46

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered '2019'	System	04 Sep 2020 19:24:21

US3552331

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered 'Jun 2019'	System	04 Sep 2020 19:24:21

US3552331

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered '2019'	System	04 Sep 2020 19:24:21

US3552331

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:13:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Eczema, LLT: Eczema - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:26:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:26:41
Data point term sent to Coder	System	04 Sep 2020 19:25:14
User entered 'eczema'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:24:36

US3552331

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered 'un UNK 1981'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:24:36

US3552331

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:13:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered '0'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:24:36

US3552331

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:13:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:24:36

US3552331

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered empty.	Stanley Doublin (b) (4)	04 Sep 2020 19:24:36
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:13:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered '0'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:24:36

US3552331

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered 'Jan 1981'	System	04 Sep 2020 19:24:36

US3552331

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered '1981'	System	04 Sep 2020 19:24:36

US3552331

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered empty.	System	04 Sep 2020 19:24:36

US3552331

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered empty.	System	04 Sep 2020 19:24:36

US3552331

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:13:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergy to antibiotic - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 18:32:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 18:32:53
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to antibiotics - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:26:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:26:41
Data point term sent to Coder	System	04 Sep 2020 19:25:15
User entered 'augmentin allergy'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:25:02

US3552331

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered 'un UNK 1989'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:25:02

US3552331

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:13:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered '0'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:25:02

US3552331

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:13:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:25:02

US3552331

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered empty.	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:25:02

US3552331

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:13:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered '0'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:25:02

US3552331

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered 'Jan 1989'	System	04 Sep 2020 19:25:02

US3552331

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:13:46

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered '1989'	System	04 Sep 2020 19:25:02

US3552331

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered empty.	System	04 Sep 2020 19:25:02

US3552331

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered empty.	System	04 Sep 2020 19:25:02

US3552331

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:13:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:26:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:26:41
Data point term sent to Coder	System	04 Sep 2020 19:25:17
User entered 'seasonal allergy'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:25:16

US3552331

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered 'un UNK 2001'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:25:16

US3552331

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:13:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered '0'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:25:16

US3552331

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:13:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:25:16

US3552331

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	30 Sep 2020 16:13:40
User entered empty.	Stanley Doublin (b) (4)	04 Sep 2020 19:25:16
	(b) (4)	

US3552331

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:13:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered '0'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:25:16

US3552331

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered 'Jan 2001'	System	04 Sep 2020 19:25:16

US3552331

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered '2001'	System	04 Sep 2020 19:25:16

US3552331

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered empty.	System	04 Sep 2020 19:25:16

US3552331

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered empty.	System	04 Sep 2020 19:25:16

US3552331

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:13:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:26:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:26:42
Data point term sent to Coder	System	04 Sep 2020 19:26:17
User entered 'obesity'	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:25:35

US3552331

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered 'un UNK 2008'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:25:35

US3552331

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:13:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered '0'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:25:35

US3552331

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:13:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:25:35

US3552331

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered 'un UNK 2009'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:25:35

US3552331

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:13:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered '0'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:25:35

US3552331

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered 'Jan 2008'	System	04 Sep 2020 19:25:35

US3552331

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:13:46

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered '2008'	System	04 Sep 2020 19:25:35

US3552331

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered 'Jan 2009'	System	04 Sep 2020 19:25:35

US3552331

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered '2009'	System	04 Sep 2020 19:25:35

US3552331

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:13:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User coded data point as SOC: Surgical and medical procedures, HLG: Gastrointestinal therapeutic procedures, HLT: Gastric therapeutic procedures, PT: Gastrectomy, LLT: Sleeve gastrectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:27:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:27:15
Data point term sent to Coder	System	04 Sep 2020 19:26:21
User entered 'gastric sleeve'	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:25:59

US3552331

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	30 Sep 2020 16:13:40
User entered 'un UNK 2009'	(b) (4), (b) (6)	30 Sep 2020 16:13:40
	Stanley Doublin (b) (4)	04 Sep 2020 19:25:59
	(b) (4)	

US3552331

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:13:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered '0'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:25:59

US3552331

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:13:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:25:59

US3552331

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered 'un UNK 2009'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:25:59

US3552331

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:13:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:13:40
User entered '0'	Stanley Doublin (b) (4)	04 Sep 2020 19:25:59

US3552331

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered 'Jan 2009'	System	04 Sep 2020 19:25:59

US3552331

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:13:46

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered '2009'	System	04 Sep 2020 19:25:59

US3552331

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered 'Jan 2009'	System	04 Sep 2020 19:25:59

US3552331

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered '2009'	System	04 Sep 2020 19:25:59

US3552331

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:13:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:14:26
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 04:15:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 04:15:41
Data point term sent to Coder	System	30 Sep 2020 17:54:05
User entered 'airplane flight anxiety'	Joan Siegner (b) (4) (b) (4)	30 Sep 2020 17:53:32

US3552331

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:14:27
User entered 'un UNK 2006' reason for change: Data Entry Error	Joan Siegner (b) (4)	08 Oct 2020 16:41:58
User entered empty.	Joan Siegner (b) (4)	30 Sep 2020 17:53:32

US3552331

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:13:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	27 Oct 2020 20:14:28
User entered '0' reason for change: Data Entry Error	Joan Siegner (b) (4)	08 Oct 2020 16:41:58
User entered '1'	Joan Siegner (b) (4)	30 Sep 2020 17:53:32

US3552331

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:13:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:14:29
User entered 'Yes (Y)'	Joan Siegner (b) (4) (b) (4)	30 Sep 2020 17:53:32

US3552331

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:14:31
User entered empty.	Joan Siegner (b) (4) (b) (4)	30 Sep 2020 17:53:32

US3552331

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:13:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:14:32
User entered '0'	Joan Siegner (b) (4)	30 Sep 2020 17:53:32

US3552331

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered 'Jan 2006'	System	08 Oct 2020 16:41:58
User entered empty.	System	30 Sep 2020 17:53:32

US3552331

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:13:46

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered '2006'	System	08 Oct 2020 16:41:58
User entered empty.	System	30 Sep 2020 17:53:32

US3552331

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered empty.	System	30 Sep 2020 17:53:32

US3552331

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered empty.	System	30 Sep 2020 17:53:32

US3552331

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:13:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:14:51
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 23:24:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 23:24:49
Data point term sent to Coder	System	08 Oct 2020 16:42:28
User entered 'depression'	Joan Siegner (b) (4)	08 Oct 2020 16:41:40

US3552331

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:14:53
User entered 'un UNK 2008'	Joan Siegner (b) (4)	08 Oct 2020 16:41:40

US3552331

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:13:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:14:55
User entered '0'	Joan Siegner (b) (4) [REDACTED]	08 Oct 2020 16:41:40

US3552331

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:13:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:14:56
User entered 'Yes (Y)'	Joan Siegner (b) (4) (b) (4)	08 Oct 2020 16:41:40

US3552331

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	27 Oct 2020 20:14:58
User entered empty.	Joan Siegner (b) (4)	08 Oct 2020 16:41:40

US3552331

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:13:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:14:59
User entered '0'	Joan Siegner (b) (4) (b) (4)	08 Oct 2020 16:41:40

US3552331

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered 'Jan 2008'	System	08 Oct 2020 16:41:40

US3552331

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered '2008'	System	08 Oct 2020 16:41:40

US3552331

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered empty.	System	08 Oct 2020 16:41:40

US3552331

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered empty.	System	08 Oct 2020 16:41:40

US3552331

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:31
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:26:38

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	10 Nov 2020 20:34:56
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 20:34:56
	Cassandra Zehenny (b) (4)	09 Nov 2020 16:22:14
User entered '04 Sep 2020' reason for change: Data Entry Error	(b) (4)	09 Nov 2020 16:22:14
DataPoint Verified.	Cassandra Zehenny (b) (4)	09 Nov 2020 16:22:14
	(b) (4)	30 Sep 2020 16:18:31
User entered '4 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 16:18:31
	Stanley Dublin (b) (4)	04 Sep 2020 19:26:38
	(b) (4)	04 Sep 2020 19:26:38

US3552331

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:31
User entered '11:27'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:26:38

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered '04 Sep 2020 11:27'	System	09 Nov 2020 16:22:14
User entered '4 Sep 2020 11:27'	System	04 Sep 2020 19:26:38

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Sep 2020 16:18:31
User entered '70' in	Stanley Doublin (b) (4)	04 Sep 2020 19:26:38
DataPoint set to visible.	(b) (4)	
	System	04 Sep 2020 17:08:10

US3552331

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Sep 2020 16:18:31
User entered '199' lb	Stanley Doublin (b) (4)	04 Sep 2020 19:26:38
	(b) (4)	
DataPoint set to visible.	System	04 Sep 2020 17:08:10

US3552331

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered '28.61323'	System	04 Sep 2020 19:26:38
DataPoint set to visible.	System	04 Sep 2020 17:08:10

US3552331

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered 'kg/m2'	System	04 Sep 2020 19:26:38
DataPoint set to visible.	System	04 Sep 2020 17:08:10

US3552331

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:31
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:26:38

US3552331

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:31
User entered empty.	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:26:38

US3552331

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	30 Sep 2020 16:18:31
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 16:18:31
	Stanley Doublin (b) (4)	04 Sep 2020 19:26:38
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:31
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:26:38

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered 'bpm'	System	04 Sep 2020 19:26:38

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:31
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:26:38

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered 'breaths/min'	System	04 Sep 2020 19:26:38

US3552331

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:31
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:26:38

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered 'mmHg'	System	04 Sep 2020 19:26:38

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:18:31
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:26:38

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered 'mmHg'	System	04 Sep 2020 19:26:38

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

[Height \(derived\)](#)

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

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

Weight (derived)

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

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Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Sep 2020 16:20:27
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	04 Sep 2020 19:27:02
	(b) (4)	

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Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	10 Nov 2020 20:35:04
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 20:35:04
	Cassandra Zehenny (b) (4)	09 Nov 2020 16:22:22
User entered '04 Sep 2020' reason for change: Data Entry Error	(b) (4)	09 Nov 2020 16:22:22
DataPoint Verified.	Cassandra Zehenny (b) (4)	09 Nov 2020 16:22:22
	(b) (4)	30 Sep 2020 16:20:27
User entered '4 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 16:20:27
	Stanley Dublin (b) (4)	04 Sep 2020 19:27:02
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:13:46

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	10 Nov 2020 20:35:10
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 20:35:10
	Cassandra Zehenny (b) (4)	09 Nov 2020 16:22:32
User entered '04 Sep 2020' reason for change: Data Entry Error	(b) (4)	09 Nov 2020 16:22:32
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:34
User entered '4 Sep 2020'	Stanley Dublin (b) (4)	04 Sep 2020 19:27:15
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:34
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:27:15

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:34
User entered empty.	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:27:15

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:34
User entered empty.	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:27:15

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:34
User entered empty.	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:27:15

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:13:46

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Sep 2020 16:20:34
User entered '0'	Stanley Doublin (b) (4)	04 Sep 2020 19:27:15
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:34
User entered empty.	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:27:15

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:13:46

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:34
User entered '0'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:27:15

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Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:42
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:27:30

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Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:35:18
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:22:40
User entered '04 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:22:40
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:42
User entered '4 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:27:30

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Folder: Screening

Form: Pregnancy Test

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[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:42
User entered 'Urine (URINE)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:27:30

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Folder: Screening

Form: Pregnancy Test

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[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:42
User entered 'Negative (NEGATIVE)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:27:30

US3552331

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:42
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:27:30

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Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:42
User entered empty.	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:27:30

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Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:20:42
User entered empty.	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:27:30

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Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User entered empty.	System	04 Sep 2020 19:27:30

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:46

[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 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:12:51
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:28:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:46

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 18:36:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	30 Sep 2020 16:12:51
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 16:12:51
	Stanley Doublin (b) (4)	04 Sep 2020 19:28:28
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:12:51
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:28:28

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Folder: Screening

Form: Risk of Exposure

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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 18:36:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:12:51
User entered 'No (N)'	Stanley Doublin (b) (4)	04 Sep 2020 19:28:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:46

[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 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:12:51
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:28:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:46

[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 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:12:51
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:28:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:46

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 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:12:51
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:28:28

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Folder: Screening

Form: Risk of Exposure

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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 18:36:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:12:51
User entered 'No (N)'	Stanley Doublin (b) (4)	04 Sep 2020 19:28:28

US3552331

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:46

[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 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:12:51
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:28:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:46

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 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:12:51
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:28:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:46

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 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:12:51
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:28:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	30 Sep 2020 16:12:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 16:12:51
	Stanley Doublin (b) (4)	04 Sep 2020 19:28:28
	(b) (4)	

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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 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:12:51
User entered 'teenage children attending in house school'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:28:28

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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 18:36:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:28:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:46

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:12:51
User entered '0'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:28:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:46

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 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:12:51
User entered 'l'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:28:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:46

[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 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:12:51
User entered '0'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:28:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:46

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 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:12:51
User entered '0'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:28:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	30 Sep 2020 16:12:51
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 16:12:51
	Stanley Doublin (b) (4)	04 Sep 2020 19:28:28
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:28:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:46

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:36:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:12:51
User entered empty.	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:28:28

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:13:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:21:01
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:28:42

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:35:27
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:22:50
User entered '04 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:22:50
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:21:01
User entered '4 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:28:42

US3552331

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:13:46

[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 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:21:01
User entered 'Clinic (Clinic)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:28:42

US3552331

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:13:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered 'VISIT1'	System	04 Sep 2020 19:28:42

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	30 Sep 2020 16:21:09
User entered '04 SEP 2020'	(b) (4), (b) (6)	30 Sep 2020 16:21:09
	RWS_ENDPOINT	04 Sep 2020 17:09:42
	ENDPOINT (b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	30 Sep 2020 16:21:09
User entered '111900'	(b) (4), (b) (6)	30 Sep 2020 16:21:09
	RWS_ENDPOINT	04 Sep 2020 17:09:42
	ENDPOINT (b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:21:09
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 17:09:42

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:13:46

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 10:36:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	30 Sep 2020 16:21:09
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 16:21:09
	Stanley Doublin (b) (4)	04 Sep 2020 19:28:53
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:13:46

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 10:36:24
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:21:09
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:28:53

US3552331

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:21:09
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:28:53

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:13:46

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:21:09
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:28:53

US3552331

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:13:46

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:21:09
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:28:53

US3552331

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	30 Sep 2020 16:21:09
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 16:21:09
	Stanley Doublin (b) (4)	21 Sep 2020 17:56:13
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:25:32
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:25:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:13:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:23:13
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:29:46

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:13:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:23:13
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:29:46

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:13:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:23:13
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:29:46

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:13:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:23:13
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:29:46

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:29:46

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:23:13
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:29:46

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:35:38
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:23:02
User entered '04 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:23:02
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:23:13
User entered '4 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:29:46

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:23:13
User entered '11:27'	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:29:46

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered '04 Sep 2020 11:27'	System	09 Nov 2020 16:23:02
User entered '4 Sep 2020 11:27'	System	04 Sep 2020 19:29:46

US3552331

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:23:13
User entered '98.4' F	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:29:46

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:23:13
User entered 'Oral (Oral)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:29:46

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:23:13
User entered empty.	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:29:46

US3552331

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:23:13
User entered '82'	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:29:46

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered 'bpm'	System	04 Sep 2020 19:29:46

US3552331

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:23:13
User entered '16'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:29:46

US3552331

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered 'breaths/min'	System	04 Sep 2020 19:29:46

US3552331

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:23:13
User entered '107'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:29:46

US3552331

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered 'mmHg'	System	04 Sep 2020 19:29:46

US3552331

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:23:13
User entered '71'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:29:46

US3552331

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered 'mmHg'	System	04 Sep 2020 19:29:46

US3552331

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:13:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:23:13
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:29:46

US3552331

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:13:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:23:13
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:29:46

US3552331

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:30:24

US3552331

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:23:13
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:30:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	10 Nov 2020 20:35:42
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 20:35:42
	Cassandra Zehenny (b) (4)	09 Nov 2020 16:23:02
User entered '04 Sep 2020' reason for change: Data Entry Error	(b) (4)	09 Nov 2020 16:23:02
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:23:13
User entered '4 Sep 2020'	Stanley Dublin (b) (4)	04 Sep 2020 19:30:24
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:23:13
User entered '13:06'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:30:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered '04 Sep 2020 13:06'	System	09 Nov 2020 16:23:02
User entered '4 Sep 2020 13:06'	System	04 Sep 2020 19:30:24

US3552331

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:23:13
User entered '98.3' F	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:30:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:23:13
User entered 'Oral (Oral)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:30:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:23:13
User entered empty.	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:30:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:23:13
User entered '68'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:30:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered 'bpm'	System	04 Sep 2020 19:30:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:23:13
User entered '14'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:30:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered 'breaths/min'	System	04 Sep 2020 19:30:24

US3552331

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:23:13
User entered '106'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:30:24

US3552331

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered 'mmHg'	System	04 Sep 2020 19:30:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:23:13
User entered '71'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:30:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered 'mmHg'	System	04 Sep 2020 19:30:24

US3552331

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:23:20
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:30:30

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:23:20
User entered empty.	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:30:30

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:23:27
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:30:35

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:23:27
User entered empty.	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:30:35

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:23:27
User entered empty.	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:30:35

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:23:27
User entered empty.	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:30:35

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:23:27
User closed query 'Per CDM: Response is required at this field. Please consider to update else clarify.' (Site from DM).		14 Sep 2020 03:54:36
Query 'Per CDM: Response is required at this field. Please consider to update else clarify.' answered with 'Updated per query request' (Site from DM).	Heather Douds (b) (4) (b) (4)	09 Sep 2020 14:08:12
User entered 'No (N)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	09 Sep 2020 14:08:08
User opened query 'Per CDM: Response is required at this field. Please consider to update else clarify.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 08:32:46
User entered empty.	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:30:35

US3552331

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:23:27
User entered empty.	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:30:35

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:23:27
User entered empty.	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:30:35

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered empty.	System	04 Sep 2020 19:30:35

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:24:03
User entered 'Yes (Y)'		04 Sep 2020 17:39:31

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	30 Sep 2020 16:24:03
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 17:39:31

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

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 10:36:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	30 Sep 2020 16:24:03
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 17:39:31

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 17:39:31

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:35:55
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:23:14
User entered '04 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:23:14
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:24:03
User entered '4 Sep 2020'		04 Sep 2020 17:39:31

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	30 Sep 2020 16:24:03
User entered '12:35'	(b) (4), (b) (6)	04 Sep 2020 17:39:31

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered '04 Sep 2020 12:35'	System	09 Nov 2020 16:23:14
User entered '4 Sep 2020 12:35'	System	04 Sep 2020 17:39:31

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:24:03
User entered 'Left Arm (LEFT ARM)'		04 Sep 2020 17:39:31

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
DataPoint Verified.		30 Sep 2020 16:24:03
User entered 'ONCE'	System	04 Sep 2020 17:39:31

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 17:39:31

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:24:11
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:30:51

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:36:02
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:23:20
User entered '04 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:23:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:24:11
User entered '4 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:30:51

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:24:11
User entered '12:00'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:30:51

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered '04 Sep 2020 12:00'	System	09 Nov 2020 16:23:20
User entered '4 Sep 2020 12:00'	System	04 Sep 2020 19:30:51

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:13:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:36:11
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:23:26
User entered '04 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:23:26
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:24:21
User entered '4 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:31:02

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:13:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:31:02

US3552331

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:13:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:24:21
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:31:02

US3552331

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:13:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:24:21
User entered '12:05'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:31:02

US3552331

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User entered '04 Sep 2020 12:05'	System	09 Nov 2020 16:23:26
User entered '4 Sep 2020 12:05'	System	04 Sep 2020 19:31:02

US3552331

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:13:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:31:02

US3552331

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:13:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:24:21
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:31:02

US3552331

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:13:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:24:21
User entered empty.	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:31:02

US3552331

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User entered empty.	System	04 Sep 2020 19:31:02

US3552331

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:24:28
User entered 'Yes (Y)'	Joan Siegner (b) (4) [REDACTED]	11 Sep 2020 18:08:14

US3552331

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User entered 'I'	System	11 Sep 2020 18:08:14

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
Data entry locked.	System	04 Sep 2020 17:39:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-04T13:04:58', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '40c3a90a-ac24-4928-a463-021710205959'	System	04 Sep 2020 18:05:27
User entered 'Yes (Y)'	System	04 Sep 2020 18:05:27

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-04T13:05:09', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '40c3a90a-ac24-4928-a463-021710205959' User entered '98.3'	System	04 Sep 2020 18:05:27
	System	04 Sep 2020 18:05:27

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-04T13:05:12', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '40c3a90a-ac24-4928-a463-021710205959'	System	04 Sep 2020 18:05:27
User entered 'No (N)'	System	04 Sep 2020 18:05:27

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-04T13:05:23', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '40c3a90a-ac24-4928-a463-021710205959'	System	04 Sep 2020 18:05:27
User entered '04 Sep 2020 13:05'	System	04 Sep 2020 18:05:27

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '04 Sep 2020 12:55'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '04 Sep 2020 15:25'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
Data entry locked.	System	04 Sep 2020 17:39:31
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-04T20:23:45', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'efef0bc6-53d9-4b8e-af55-76ee00474a89'	System	05 Sep 2020 01:24:03
User entered 'Yes (Y)'	System	05 Sep 2020 01:24:03

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-04T20:23:51', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'efef0bc6-53d9-4b8e-af55-76ee00474a89'	System	05 Sep 2020 01:24:03
User entered '97.7'	System	05 Sep 2020 01:24:03

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-04T20:23:55', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'efef0bc6-53d9-4b8e-af55-76ee00474a89'	System	05 Sep 2020 01:24:03
User entered 'No (N)'	System	05 Sep 2020 01:24:03

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-04T20:23:58', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'efef0bc6-53d9-4b8e-af55-76ee00474a89'	System	05 Sep 2020 01:24:03
User entered '04 Sep 2020 20:23'	System	05 Sep 2020 01:24:03

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '04 Sep 2020 16:20'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
Data entry locked.	System	04 Sep 2020 17:39:31
User entered 'Day 2'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-05T18:49:56', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'f45f638f-5a63-4750-8891-435af99422db'	System	05 Sep 2020 23:50:25
User entered 'Yes (Y)'	System	05 Sep 2020 23:50:25

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-05T18:50:01', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'f45f638f-5a63-4750-8891-435af99422db'	System	05 Sep 2020 23:50:25
User entered '97.4'	System	05 Sep 2020 23:50:25

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-05T18:50:18', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'f45f638f-5a63-4750-8891-435af99422db'	System	05 Sep 2020 23:50:25
User entered 'No (N)'	System	05 Sep 2020 23:50:25

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-05T18:50:22', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'f45f638f-5a63-4750-8891-435af99422db'	System	05 Sep 2020 23:50:25
User entered '05 Sep 2020 18:50'	System	05 Sep 2020 23:50:25

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
Data entry locked.	System	04 Sep 2020 17:39:31
User entered 'Day 3'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-06T18:33:02', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'f20f398d-0cc3-4de7-b32c-bd20719d68ec'	System	06 Sep 2020 23:33:18
User entered 'Yes (Y)'	System	06 Sep 2020 23:33:18

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-06T18:33:08', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'f20f398d-0cc3-4de7-b32c-bd20719d68ec'	System	06 Sep 2020 23:33:18
User entered '97.8'	System	06 Sep 2020 23:33:18

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-06T18:33:13', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'f20f398d-0cc3-4de7-b32c-bd20719d68ec'	System	06 Sep 2020 23:33:18
User entered 'No (N)'	System	06 Sep 2020 23:33:18

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-06T18:33:16', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'f20f398d-0cc3-4de7-b32c-bd20719d68ec'	System	06 Sep 2020 23:33:18
User entered '06 Sep 2020 18:33'	System	06 Sep 2020 23:33:18

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
Data entry locked.	System	04 Sep 2020 17:39:31
User entered 'Day 4'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-07T20:55:24', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '886f1140-5fc6-4c4f-9a17-4c00082b25a7'	System	08 Sep 2020 01:56:07
User entered 'Yes (Y)'	System	08 Sep 2020 01:56:07

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-07T20:55:54', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '886f1140-5fc6-4c4f-9a17-4c00082b25a7'	System	08 Sep 2020 01:56:07
User entered '97.4'	System	08 Sep 2020 01:56:07

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-07T20:55:57', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '886f1140-5fc6-4c4f-9a17-4c00082b25a7'	System	08 Sep 2020 01:56:07
User entered 'No (N)'	System	08 Sep 2020 01:56:07

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-07T20:56:02', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '886f1140-5fc6-4c4f-9a17-4c00082b25a7'	System	08 Sep 2020 01:56:07
User entered '07 Sep 2020 20:56'	System	08 Sep 2020 01:56:07

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
Data entry locked.	System	04 Sep 2020 17:39:31
User entered 'Day 5'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-09T06:23:49', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '4c88f71a-8ba8-4239-b3e5-bcc41268f44c'	System	09 Sep 2020 11:24:08
User entered 'Yes (Y)'	System	09 Sep 2020 11:24:08

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-09T06:23:55', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '4c88f71a-8ba8-4239-b3e5-bcc41268f44c'	System	09 Sep 2020 11:24:08
User entered '97.8'	System	09 Sep 2020 11:24:08

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-09T06:23:58', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '4c88f71a-8ba8-4239-b3e5-bcc41268f44c'	System	09 Sep 2020 11:24:08
User entered 'No (N)'	System	09 Sep 2020 11:24:08

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-09T06:24:04', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '4c88f71a-8ba8-4239-b3e5-bcc41268f44c'	System	09 Sep 2020 11:24:08
User entered '09 Sep 2020 06:24'	System	09 Sep 2020 11:24:08

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
Data entry locked.	System	04 Sep 2020 17:39:31
User entered 'Day 6'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-10T04:15:36', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '4da5e576-122f-4f60-87fb-9c986e2e8350'	System	10 Sep 2020 09:15:54
User entered 'Yes (Y)'	System	10 Sep 2020 09:15:54

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-10T04:15:40', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '4da5e576-122f-4f60-87fb-9c986e2e8350'	System	10 Sep 2020 09:15:54
User entered '97.7'	System	10 Sep 2020 09:15:54

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-10T04:15:44', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '4da5e576-122f-4f60-87fb-9c986e2e8350'	System	10 Sep 2020 09:15:54
User entered 'No (N)'	System	10 Sep 2020 09:15:54

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-10T04:15:48', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '4da5e576-122f-4f60-87fb-9c986e2e8350'	System	10 Sep 2020 09:15:54
User entered '10 Sep 2020 04:15'	System	10 Sep 2020 09:15:54

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
Data entry locked.	System	04 Sep 2020 17:39:31
User entered 'Day 7'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-10T23:31:55', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '0958b292-4d9a-4287-b153-9d96db30c88a'	System	11 Sep 2020 04:32:13
User entered 'Yes (Y)'	System	11 Sep 2020 04:32:13

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-10T23:32:01', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '0958b292-4d9a-4287-b153-9d96db30c88a'	System	11 Sep 2020 04:32:13
User entered '98.1'	System	11 Sep 2020 04:32:13

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-10T23:32:04', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '0958b292-4d9a-4287-b153-9d96db30c88a'	System	11 Sep 2020 04:32:13
User entered 'No (N)'	System	11 Sep 2020 04:32:13

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-10T23:32:07', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '0958b292-4d9a-4287-b153-9d96db30c88a'	System	11 Sep 2020 04:32:13
User entered '10 Sep 2020 23:32'	System	11 Sep 2020 04:32:13

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
Data entry locked.	System	04 Sep 2020 17:39:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:46

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 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-04T13:05:51', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'c4e3df78-9cef-4197-a30f-c1c06a2760f2'	System	04 Sep 2020 18:06:14
User entered 'None (1)'	System	04 Sep 2020 18:06:14

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-04T13:05:54', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'c4e3df78-9cef-4197-a30f-c1c06a2760f2'	System	04 Sep 2020 18:06:14
User entered 'No (N)'	System	04 Sep 2020 18:06:14

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-04T13:05:57', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'c4e3df78-9cef-4197-a30f-c1c06a2760f2'	System	04 Sep 2020 18:06:14
User entered 'No (N)'	System	04 Sep 2020 18:06:14

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:46

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 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-04T13:06:05', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'c4e3df78-9cef-4197-a30f-c1c06a2760f2'	System	04 Sep 2020 18:06:14
User entered 'None (1)'	System	04 Sep 2020 18:06:14

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-04T13:06:09', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'c4e3df78-9cef-4197-a30f-c1c06a2760f2'	System	04 Sep 2020 18:06:14
User entered '04 Sep 2020 13:06'	System	04 Sep 2020 18:06:14

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '04 Sep 2020 12:55'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '04 Sep 2020 15:25'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
Data entry locked.	System	04 Sep 2020 17:39:31
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:46

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 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-04T20:24:05', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'a473fcee-42f8-405f-89f8-482a9e2b8fae'	System	05 Sep 2020 01:24:31
User entered 'None (1)'	System	05 Sep 2020 01:24:31

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-04T20:24:09', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'a473fcee-42f8-405f-89f8-482a9e2b8fae'	System	05 Sep 2020 01:24:31
User entered 'No (N)'	System	05 Sep 2020 01:24:31

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-04T20:24:12', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'a473fcee-42f8-405f-89f8-482a9e2b8fae'	System	05 Sep 2020 01:24:31
User entered 'No (N)'	System	05 Sep 2020 01:24:31

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:46

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 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-04T20:24:21', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'a473fcee-42f8-405f-89f8-482a9e2b8fae'	System	05 Sep 2020 01:24:31
User entered 'None (1)'	System	05 Sep 2020 01:24:31

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-04T20:24:25', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'a473fcee-42f8-405f-89f8-482a9e2b8fae'	System	05 Sep 2020 01:24:31
User entered '04 Sep 2020 20:24'	System	05 Sep 2020 01:24:31

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '04 Sep 2020 16:20'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
Data entry locked.	System	04 Sep 2020 17:39:31
User entered 'Day 2'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:46

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 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-05T18:51:08', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '36728db4-55e0-406a-80c4-9fb496d6394e'	System	05 Sep 2020 23:52:01
User entered 'None (1)'	System	05 Sep 2020 23:52:01

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-05T18:51:16', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '36728db4-55e0-406a-80c4-9fb496d6394e'	System	05 Sep 2020 23:52:01
User entered 'No (N)'	System	05 Sep 2020 23:52:01

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-05T18:51:50', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '36728db4-55e0-406a-80c4-9fb496d6394e'	System	05 Sep 2020 23:52:01
User entered 'No (N)'	System	05 Sep 2020 23:52:01

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:46

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 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-05T18:51:54', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '36728db4-55e0-406a-80c4-9fb496d6394e'	System	05 Sep 2020 23:52:01
User entered 'None (1)'	System	05 Sep 2020 23:52:01

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-05T18:51:58', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '36728db4-55e0-406a-80c4-9fb496d6394e'	System	05 Sep 2020 23:52:01
User entered '05 Sep 2020 18:51'	System	05 Sep 2020 23:52:01

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
Data entry locked.	System	04 Sep 2020 17:39:31
User entered 'Day 3'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:46

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 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-06T18:33:21', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'c95f2498-f178-4382-aff0-a606cd2b4be1'	System	06 Sep 2020 23:33:43
User entered 'None (1)'	System	06 Sep 2020 23:33:43

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-06T18:33:26', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'c95f2498-f178-4382-aff0-a606cd2b4be1'	System	06 Sep 2020 23:33:43
User entered 'No (N)'	System	06 Sep 2020 23:33:43

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-06T18:33:31', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'c95f2498-f178-4382-aff0-a606cd2b4be1'	System	06 Sep 2020 23:33:43
User entered 'No (N)'	System	06 Sep 2020 23:33:43

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:46

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 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-06T18:33:34', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'c95f2498-f178-4382-aff0-a606cd2b4be1'	System	06 Sep 2020 23:33:43
User entered 'None (1)'	System	06 Sep 2020 23:33:43

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-06T18:33:37', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'c95f2498-f178-4382-aff0-a606cd2b4be1'	System	06 Sep 2020 23:33:43
User entered '06 Sep 2020 18:33'	System	06 Sep 2020 23:33:43

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
Data entry locked.	System	04 Sep 2020 17:39:31
User entered 'Day 4'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:46

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 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-07T20:56:11', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '3574073a-6dfc-4165-a952-ac9441bac401'	System	08 Sep 2020 01:56:27
User entered 'None (1)'	System	08 Sep 2020 01:56:27

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-07T20:56:14', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '3574073a-6dfc-4165-a952-ac9441bac401'	System	08 Sep 2020 01:56:27
User entered 'No (N)'	System	08 Sep 2020 01:56:27

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-07T20:56:16', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '3574073a-6dfc-4165-a952-ac9441bac401'	System	08 Sep 2020 01:56:27
User entered 'No (N)'	System	08 Sep 2020 01:56:27

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:46

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 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-07T20:56:19', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '3574073a-6dfc-4165-a952-ac9441bac401'	System	08 Sep 2020 01:56:27
User entered 'None (1)'	System	08 Sep 2020 01:56:27

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-07T20:56:22', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '3574073a-6dfc-4165-a952-ae9441bac401'	System	08 Sep 2020 01:56:27
User entered '07 Sep 2020 20:56'	System	08 Sep 2020 01:56:27

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
Data entry locked.	System	04 Sep 2020 17:39:31
User entered 'Day 5'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:46

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 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-09T06:24:08', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '45b05605-bc45-4b32-aa6d-ea9c9aa9cd89'	System	09 Sep 2020 11:24:22
User entered 'None (1)'	System	09 Sep 2020 11:24:22

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-09T06:24:11', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '45b05605-bc45-4b32-aa6d-ea9c9aa9cd89'	System	09 Sep 2020 11:24:22
User entered 'No (N)'	System	09 Sep 2020 11:24:22

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-09T06:24:13', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '45b05605-bc45-4b32-aa6d-ea9c9aa9cd89'	System	09 Sep 2020 11:24:22
User entered 'No (N)'	System	09 Sep 2020 11:24:22

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:46

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 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-09T06:24:16', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '45b05605-bc45-4b32-aa6d-ea9c9aa9cd89'	System	09 Sep 2020 11:24:22
User entered 'None (1)'	System	09 Sep 2020 11:24:22

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-09T06:24:18', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '45b05605-bc45-4b32-aa6d-ea9c9aa9cd89'	System	09 Sep 2020 11:24:22
User entered '09 Sep 2020 06:24'	System	09 Sep 2020 11:24:22

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
Data entry locked.	System	04 Sep 2020 17:39:31
User entered 'Day 6'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:46

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 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-10T04:15:52', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '4f44d951-7f1e-4ac6-9ef9-f75310207e6e'	System	10 Sep 2020 09:16:07
User entered 'None (1)'	System	10 Sep 2020 09:16:07

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-10T04:15:55', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '4f44d951-7f1e-4ac6-9ef9-f75310207e6e'	System	10 Sep 2020 09:16:07
User entered 'No (N)'	System	10 Sep 2020 09:16:07

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-10T04:15:58', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '4f44d951-7f1e-4ac6-9ef9-f75310207e6e'	System	10 Sep 2020 09:16:07
User entered 'No (N)'	System	10 Sep 2020 09:16:07

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:46

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 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-10T04:16:00', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '4f44d951-7f1e-4ac6-9ef9-f75310207e6e'	System	10 Sep 2020 09:16:07
User entered 'None (1)'	System	10 Sep 2020 09:16:07

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-10T04:16:03', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '4f44d951-7f1e-4ac6-9ef9-f75310207e6e'	System	10 Sep 2020 09:16:07
User entered '10 Sep 2020 04:16'	System	10 Sep 2020 09:16:07

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
Data entry locked.	System	04 Sep 2020 17:39:31
User entered 'Day 7'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:46

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 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-10T23:32:10', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '420ea2b4-d1b8-46d8-954a-52a1aa68d5eb'	System	11 Sep 2020 04:32:25
User entered 'None (1)'	System	11 Sep 2020 04:32:25

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-10T23:32:14', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '420ea2b4-d1b8-46d8-954a-52a1aa68d5eb'	System	11 Sep 2020 04:32:25
User entered 'No (N)'	System	11 Sep 2020 04:32:25

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-10T23:32:16', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '420ea2b4-d1b8-46d8-954a-52a1aa68d5eb'	System	11 Sep 2020 04:32:25
User entered 'No (N)'	System	11 Sep 2020 04:32:25

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:46

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 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-10T23:32:18', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '420ea2b4-d1b8-46d8-954a-52a1aa68d5eb'	System	11 Sep 2020 04:32:25
User entered 'None (1)'	System	11 Sep 2020 04:32:25

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-10T23:32:21', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '420ea2b4-d1b8-46d8-954a-52a1aa68d5eb'	System	11 Sep 2020 04:32:25
User entered '10 Sep 2020 23:32'	System	11 Sep 2020 04:32:25

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
Data entry locked.	System	04 Sep 2020 17:39:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-04T13:06:15', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '3ae0563a-0352-4a10-bee7-ad922abef96b'	System	04 Sep 2020 18:06:42
User entered 'None (0)'	System	04 Sep 2020 18:06:42

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-04T13:06:18', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '3ae0563a-0352-4a10-bee7-ad922abef96b'	System	04 Sep 2020 18:06:42
User entered 'None (0)'	System	04 Sep 2020 18:06:42

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-04T13:06:21', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '3ae0563a-0352-4a10-bee7-ad922abef96b'	System	04 Sep 2020 18:06:42
User entered 'None (0)'	System	04 Sep 2020 18:06:42

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-04T13:06:24', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '3ae0563a-0352-4a10-bee7-ad922abef96b'	System	04 Sep 2020 18:06:42
User entered 'None (0)'	System	04 Sep 2020 18:06:42

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-04T13:06:26', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '3ae0563a-0352-4a10-bee7-ad922abef96b'	System	04 Sep 2020 18:06:42
User entered 'None (0)'	System	04 Sep 2020 18:06:42

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-04T13:06:28', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '3ae0563a-0352-4a10-bee7-ad922abef96b'	System	04 Sep 2020 18:06:42
User entered 'None (0)'	System	04 Sep 2020 18:06:42

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:46

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 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-04T13:06:32', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '3ae0563a-0352-4a10-bee7-ad922abef96b'	System	04 Sep 2020 18:06:42
User entered 'No (N)'	System	04 Sep 2020 18:06:42

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-04T13:06:36', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '3ae0563a-0352-4a10-bee7-ad922abef96b'	System	04 Sep 2020 18:06:42
User entered '04 Sep 2020 13:06'	System	04 Sep 2020 18:06:42

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '04 Sep 2020 12:55'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '04 Sep 2020 15:25'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
Data entry locked.	System	04 Sep 2020 17:39:31
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-04T20:24:36', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '3abf7d35-4395-4b8f-8213-eedf4affd970'	System	05 Sep 2020 01:25:04
User entered 'None (0)'	System	05 Sep 2020 01:25:04

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-04T20:24:46', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '3abf7d35-4395-4b8f-8213-eedf4affd970'	System	05 Sep 2020 01:25:04
User entered 'None (0)'	System	05 Sep 2020 01:25:04

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-04T20:24:48', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '3abf7d35-4395-4b8f-8213-eedf4affd970'	System	05 Sep 2020 01:25:04
User entered 'None (0)'	System	05 Sep 2020 01:25:04

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-04T20:24:50', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '3abf7d35-4395-4b8f-8213-eedf4affd970'	System	05 Sep 2020 01:25:04
User entered 'None (0)'	System	05 Sep 2020 01:25:04

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-04T20:24:52', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '3abf7d35-4395-4b8f-8213-eedf4affd970'	System	05 Sep 2020 01:25:04
User entered 'None (0)'	System	05 Sep 2020 01:25:04

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-04T20:24:54', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '3abf7d35-4395-4b8f-8213-eedf4affd970'	System	05 Sep 2020 01:25:04
User entered 'None (0)'	System	05 Sep 2020 01:25:04

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:46

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 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-04T20:24:56', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '3abf7d35-4395-4b8f-8213-eedf4affd970'	System	05 Sep 2020 01:25:04
User entered 'No (N)'	System	05 Sep 2020 01:25:04

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-04T20:25:00', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '3abf7d35-4395-4b8f-8213-eedf4affd970'	System	05 Sep 2020 01:25:04
User entered '04 Sep 2020 20:25'	System	05 Sep 2020 01:25:04

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '04 Sep 2020 16:20'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
Data entry locked.	System	04 Sep 2020 17:39:31
User entered 'Day 2'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-05T18:52:02', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '9f05bd62-d296-4a1c-a006-cf1f5e975c6d'	System	05 Sep 2020 23:52:38
User entered 'None (0)'	System	05 Sep 2020 23:52:38

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-05T18:52:11', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '9f05bd62-d296-4a1c-a006-cf1f5e975c6d'	System	05 Sep 2020 23:52:38
User entered 'None (0)'	System	05 Sep 2020 23:52:38

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-05T18:52:13', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '9f05bd62-d296-4a1c-a006-cf1f5e975c6d'	System	05 Sep 2020 23:52:38
User entered 'None (0)'	System	05 Sep 2020 23:52:38

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-05T18:52:17', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '9f05bd62-d296-4a1c-a006-cf1f5e975c6d'	System	05 Sep 2020 23:52:38
User entered 'None (0)'	System	05 Sep 2020 23:52:38

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-05T18:52:20', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '9f05bd62-d296-4a1c-a006-cf1f5e975c6d'	System	05 Sep 2020 23:52:38
User entered 'None (0)'	System	05 Sep 2020 23:52:38

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-05T18:52:23', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '9f05bd62-d296-4a1c-a006-cf1f5e975c6d'	System	05 Sep 2020 23:52:38
User entered 'None (0)'	System	05 Sep 2020 23:52:38

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:46

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 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-05T18:52:29', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '9f05bd62-d296-4a1c-a006-cf1f5e975c6d'	System	05 Sep 2020 23:52:38
User entered 'No (N)'	System	05 Sep 2020 23:52:38

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-05T18:52:32', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '9f05bd62-d296-4a1c-a006-cf1f5e975c6d'	System	05 Sep 2020 23:52:38
User entered '05 Sep 2020 18:52'	System	05 Sep 2020 23:52:38

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
Data entry locked.	System	04 Sep 2020 17:39:31
User entered 'Day 3'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-06T18:33:41', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'ef1ac243-7d5c-4837-8628-9b11485f9688'	System	06 Sep 2020 23:34:21
User entered 'None (0)'	System	06 Sep 2020 23:34:21

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-06T18:33:48', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'ef1ac243-7d5c-4837-8628-9b11485f9688'	System	06 Sep 2020 23:34:21
User entered 'None (0)'	System	06 Sep 2020 23:34:21

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-06T18:33:50', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'ef1ac243-7d5c-4837-8628-9b11485f9688'	System	06 Sep 2020 23:34:21
User entered 'None (0)'	System	06 Sep 2020 23:34:21

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-06T18:33:52', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'ef1ac243-7d5c-4837-8628-9b11485f9688'	System	06 Sep 2020 23:34:21
User entered 'None (0)'	System	06 Sep 2020 23:34:21

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-06T18:33:54', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'ef1ac243-7d5c-4837-8628-9b11485f9688'	System	06 Sep 2020 23:34:21
User entered 'None (0)'	System	06 Sep 2020 23:34:21

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-06T18:33:56', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'ef1ac243-7d5c-4837-8628-9b11485f9688'	System	06 Sep 2020 23:34:21
User entered 'None (0)'	System	06 Sep 2020 23:34:21

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:46

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 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-06T18:34:15', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'ef1ac243-7d5c-4837-8628-9b11485f9688'	System	06 Sep 2020 23:34:21
User entered 'No (N)'	System	06 Sep 2020 23:34:21

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-06T18:34:18', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'ef1ac243-7d5c-4837-8628-9b11485f9688'	System	06 Sep 2020 23:34:21
User entered '06 Sep 2020 18:34'	System	06 Sep 2020 23:34:21

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
Data entry locked.	System	04 Sep 2020 17:39:31
User entered 'Day 4'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-07T20:56:30', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'b6a0cb38-304e-4305-8a31-523ce12b837a'	System	08 Sep 2020 01:56:47
User entered 'None (0)'	System	08 Sep 2020 01:56:47

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-07T20:56:32', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'b6a0cb38-304e-4305-8a31-523ce12b837a'	System	08 Sep 2020 01:56:47
User entered 'None (0)'	System	08 Sep 2020 01:56:47

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-07T20:56:33', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'b6a0cb38-304e-4305-8a31-523ce12b837a'	System	08 Sep 2020 01:56:47
User entered 'None (0)'	System	08 Sep 2020 01:56:47

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-07T20:56:35', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'b6a0cb38-304e-4305-8a31-523ce12b837a'	System	08 Sep 2020 01:56:47
User entered 'None (0)'	System	08 Sep 2020 01:56:47

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-07T20:56:36', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'b6a0cb38-304e-4305-8a31-523ce12b837a'	System	08 Sep 2020 01:56:47
User entered 'None (0)'	System	08 Sep 2020 01:56:47

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-07T20:56:38', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'b6a0cb38-304e-4305-8a31-523ce12b837a'	System	08 Sep 2020 01:56:47
User entered 'None (0)'	System	08 Sep 2020 01:56:47

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:46

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 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-07T20:56:41', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'b6a0cb38-304e-4305-8a31-523ce12b837a'	System	08 Sep 2020 01:56:47
User entered 'No (N)'	System	08 Sep 2020 01:56:47

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-07T20:56:43', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'b6a0cb38-304e-4305-8a31-523ce12b837a'	System	08 Sep 2020 01:56:47
User entered '07 Sep 2020 20:56'	System	08 Sep 2020 01:56:47

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
Data entry locked.	System	04 Sep 2020 17:39:31
User entered 'Day 5'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-09T06:24:23', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '0ee3db38-2d7f-4f0f-a7a7-9dd0204afdfd'	System	09 Sep 2020 11:24:43
User entered 'None (0)'	System	09 Sep 2020 11:24:43

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-09T06:24:25', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '0ee3db38-2d7f-4f0f-a7a7-9dd0204afdfd'	System	09 Sep 2020 11:24:43
User entered 'None (0)'	System	09 Sep 2020 11:24:43

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-09T06:24:27', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '0ee3db38-2d7f-4f0f-a7a7-9dd0204afdfd'	System	09 Sep 2020 11:24:43
User entered 'None (0)'	System	09 Sep 2020 11:24:43

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-09T06:24:29', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '0ee3db38-2d7f-4f0f-a7a7-9dd0204afdfd'	System	09 Sep 2020 11:24:43
User entered 'None (0)'	System	09 Sep 2020 11:24:43

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-09T06:24:31', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '0ee3db38-2d7f-4f0f-a7a7-9dd0204afdfd'	System	09 Sep 2020 11:24:43
User entered 'None (0)'	System	09 Sep 2020 11:24:43

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-09T06:24:33', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '0ee3db38-2d7f-4f0f-a7a7-9dd0204afdfd'	System	09 Sep 2020 11:24:43
User entered 'None (0)'	System	09 Sep 2020 11:24:43

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:46

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 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-09T06:24:36', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '0ee3db38-2d7f-4f0f-a7a7-9dd0204afdfd'	System	09 Sep 2020 11:24:43
User entered 'No (N)'	System	09 Sep 2020 11:24:43

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-09T06:24:38', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '0ee3db38-2d7f-4f0f-a7a7-9dd0204afdfd'	System	09 Sep 2020 11:24:43
User entered '09 Sep 2020 06:24'	System	09 Sep 2020 11:24:43

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
Data entry locked.	System	04 Sep 2020 17:39:31
User entered 'Day 6'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-10T04:16:19', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '6d3e848c-e183-4b0f-bd0c-497d96f7c5d1'	System	10 Sep 2020 09:17:07
User entered 'No interference with activity (1)'	System	10 Sep 2020 09:17:07

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-10T04:16:22', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '6d3e848c-e183-4b0f-bd0c-497d96f7c5d1'	System	10 Sep 2020 09:17:07
User entered 'None (0)'	System	10 Sep 2020 09:17:07

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-10T04:16:26', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '6d3e848c-e183-4b0f-bd0c-497d96f7c5d1'	System	10 Sep 2020 09:17:07
User entered 'None (0)'	System	10 Sep 2020 09:17:07

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-10T04:16:32', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '6d3e848c-e183-4b0f-bd0c-497d96f7c5d1'	System	10 Sep 2020 09:17:07
User entered 'None (0)'	System	10 Sep 2020 09:17:07

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-10T04:16:52', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '6d3e848c-e183-4b0f-bd0c-497d96f7c5d1'	System	10 Sep 2020 09:17:07
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	10 Sep 2020 09:17:07

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-10T04:16:55', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '6d3e848c-e183-4b0f-bd0c-497d96f7c5d1'	System	10 Sep 2020 09:17:07
User entered 'None (0)'	System	10 Sep 2020 09:17:07

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:46

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 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-10T04:16:58', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '6d3e848c-e183-4b0f-bd0c-497d96f7c5d1'	System	10 Sep 2020 09:17:07
User entered 'No (N)'	System	10 Sep 2020 09:17:07

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-10T04:17:01', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '6d3e848c-e183-4b0f-bd0c-497d96f7c5d1'	System	10 Sep 2020 09:17:07
User entered '10 Sep 2020 04:17'	System	10 Sep 2020 09:17:07

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
Data entry locked.	System	04 Sep 2020 17:39:31
User entered 'Day 7'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-10T23:32:24', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'bdb1be0b-8aa2-40c1-bc28-3f80db38f205'	System	11 Sep 2020 04:32:45
User entered 'None (0)'	System	11 Sep 2020 04:32:45

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-10T23:32:26', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'bdb1be0b-8aa2-40c1-bc28-3f80db38f205'	System	11 Sep 2020 04:32:45
User entered 'None (0)'	System	11 Sep 2020 04:32:45

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-10T23:32:28', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'bdb1be0b-8aa2-40c1-bc28-3f80db38f205'	System	11 Sep 2020 04:32:45
User entered 'None (0)'	System	11 Sep 2020 04:32:45

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-10T23:32:30', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'bdb1be0b-8aa2-40c1-bc28-3f80db38f205'	System	11 Sep 2020 04:32:45
User entered 'None (0)'	System	11 Sep 2020 04:32:45

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-10T23:32:32', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'bdb1be0b-8aa2-40c1-bc28-3f80db38f205'	System	11 Sep 2020 04:32:45
User entered 'None (0)'	System	11 Sep 2020 04:32:45

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-10T23:32:35', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'bdb1be0b-8aa2-40c1-bc28-3f80db38f205'	System	11 Sep 2020 04:32:45
User entered 'None (0)'	System	11 Sep 2020 04:32:45

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:46

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 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-10T23:32:37', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'bdb1be0b-8aa2-40c1-bc28-3f80db38f205'	System	11 Sep 2020 04:32:45
User entered 'No (N)'	System	11 Sep 2020 04:32:45

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-09-10T23:32:40', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'bdb1be0b-8aa2-40c1-bc28-3f80db38f205'	System	11 Sep 2020 04:32:45
User entered '10 Sep 2020 23:32'	System	11 Sep 2020 04:32:45

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 17:39:31

US3552331

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 17:39:31

US3552331

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:24:57
User entered 'Yes (Y)'	Joan Siegner (b) (4) [REDACTED]	11 Sep 2020 18:08:27

US3552331

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:24:57
User entered '11 Sep 2020'	Joan Siegner (b) (4) (b) (4)	11 Sep 2020 18:08:27

US3552331

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:24:57
User entered 'Contact Made (CONTACT MADE)'	Joan Siegner (b) (4) [REDACTED]	11 Sep 2020 18:08:27

US3552331

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:24:57
User entered empty.	Joan Siegner (b) (4) [REDACTED]	11 Sep 2020 18:08:27

US3552331

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:25:03
User entered 'Yes (Y)'	Joan Siegner (b) (4) (b) (4)	21 Sep 2020 16:14:04

US3552331

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User entered 'l'	System	21 Sep 2020 16:14:04

US3552331

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:25:10
User entered 'Yes (Y)'	Joan Siegner (b) (4) [REDACTED]	21 Sep 2020 16:14:13

US3552331

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:25:10
User entered '21 Sep 2020'	Joan Siegner (b) (4) [REDACTED]	21 Sep 2020 16:14:13

US3552331

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:25:10
User entered 'Contact Made (CONTACT MADE)'	Joan Siegner (b) (4) (b) (4)	21 Sep 2020 16:14:13

US3552331

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:25:10
User entered empty.	Joan Siegner (b) (4) (b) (4)	21 Sep 2020 16:14:13

US3552331

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:25:17
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	25 Sep 2020 18:48:49

US3552331

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User entered 'l'	System	25 Sep 2020 18:48:49

US3552331

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:25:23
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	25 Sep 2020 18:48:57

US3552331

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:25:23
User entered '25 Sep 2020'	Mikayla Frye (b) (4) (b) (4)	25 Sep 2020 18:48:57

US3552331

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:25:23
User entered 'Contact Made (CONTACT MADE)'	Mikayla Frye (b) (4) (b) (4)	25 Sep 2020 18:48:57

US3552331

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 16:25:23
User entered empty.	Mikayla Frye (b) (4) (b) (4)	25 Sep 2020 18:48:57

US3552331

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:08:50
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	01 Oct 2020 18:28:28

US3552331

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User entered 'l'	System	01 Oct 2020 18:28:28

US3552331

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:09:44
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:46:19

US3552331

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:00
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:23:45
User entered '01 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:23:45
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:09:44
User entered '1 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 18:46:19

US3552331

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:46

[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 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:09:44
User entered 'Clinic (Clinic)'	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:46:19

US3552331

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered 'VISIT2'	System	01 Oct 2020 18:46:19

US3552331

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:46:40

US3552331

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:10:26
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:46:40

US3552331

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	11 Nov 2020 15:39:09
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:09
	Cassandra Zehenny (b) (4)	09 Nov 2020 16:23:55
User entered '01 Oct 2020' reason for change: Data Entry Error	(b) (4)	09 Nov 2020 16:23:55
DataPoint Verified.	Cassandra Zehenny (b) (4)	09 Nov 2020 16:23:55
	(b) (4)	12 Oct 2020 16:10:26
User entered '1 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 16:10:26
	Stanley Dublin (b) (4)	01 Oct 2020 18:46:40
	(b) (4)	

US3552331

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:10:26
User entered '08:35'	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:46:40

US3552331

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered '01 Oct 2020 08:35'	System	09 Nov 2020 16:23:55
User entered '1 Oct 2020 08:35'	System	01 Oct 2020 18:46:40

US3552331

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:10:26
User entered '97.9' F	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:46:40

US3552331

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:10:26
User entered 'Oral (Oral)'	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:46:40

US3552331

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:10:26
User entered empty.	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:46:40

US3552331

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:10:26
User entered '70'	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:46:40

US3552331

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered 'bpm'	System	01 Oct 2020 18:46:40

US3552331

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:10:26
User entered '16'	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:46:40

US3552331

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered 'breaths/min'	System	01 Oct 2020 18:46:40

US3552331

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:10:26
User entered '115'	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:46:40

US3552331

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered 'mmHg'	System	01 Oct 2020 18:46:40

US3552331

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:10:26
User entered '70'	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:46:40

US3552331

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered 'mmHg'	System	01 Oct 2020 18:46:40

US3552331

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:46:51

US3552331

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:10:26
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:46:51

US3552331

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:10:26
User entered empty.	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:46:51

US3552331

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:10:26
User entered empty.	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:46:51

US3552331

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered empty.	System	01 Oct 2020 18:46:51

US3552331

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:10:26
User entered empty.	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 18:46:51

US3552331

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:10:26
User entered empty.	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:46:51

US3552331

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:10:26
User entered empty.	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 18:46:51

US3552331

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:10:26
User entered empty.	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:46:51

US3552331

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered empty.	System	01 Oct 2020 18:46:51

US3552331

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:10:26
User entered empty.	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:46:51

US3552331

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered empty.	System	01 Oct 2020 18:46:51

US3552331

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:10:26
User entered empty.	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:46:51

US3552331

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered empty.	System	01 Oct 2020 18:46:51

US3552331

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:10:26
User entered empty.	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:46:51

US3552331

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered empty.	System	01 Oct 2020 18:46:51

US3552331

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:10:50
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:47:04

US3552331

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:15
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:24:02
User entered '01 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:24:02
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:10:50
User entered '1 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 18:47:04

US3552331

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:10:59
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:47:18

US3552331

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:20
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:24:07
User entered '01 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:24:07
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:10:59
User entered '1 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 18:47:18

US3552331

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:10:59
User entered 'Urine (URINE)'	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:47:18

US3552331

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:10:59
User entered 'Negative (NEGATIVE)'	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:47:18

US3552331

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:10:59
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:47:18

US3552331

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:10:59
User entered empty.	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:47:18

US3552331

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:10:59
User entered empty.	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:47:18

US3552331

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered empty.	System	01 Oct 2020 18:47:18

US3552331

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 14:59:30
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:49:38

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	09 Nov 2020 14:59:30
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	Stanley Doublin (b) (4)	01 Oct 2020 18:49:38
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

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 10:36:24
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	09 Nov 2020 14:59:30
User entered 'Recent episode of WORSENING DEPRESSION' reason for change: Data Entry Error	Heather Douds (b) (4)	01 Oct 2020 18:52:51
User entered 'worsening depression'	(b) (4)	01 Oct 2020 18:49:38
	Stanley Doublin (b) (4)	
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered empty.	System	01 Oct 2020 18:49:38

US3552331

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 14:59:30
User entered empty.	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:49:38

US3552331

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 14:59:30
User entered empty.	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:49:38

US3552331

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered empty.	System	01 Oct 2020 18:49:38

US3552331

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 14:59:30
User entered empty.	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 18:49:38

US3552331

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
DataPoint Verified.		09 Nov 2020 14:59:30
User entered empty.	System	01 Oct 2020 18:49:38

US3552331

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered empty.	System	01 Oct 2020 18:49:38

US3552331

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:22:34
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:49:59

US3552331

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:28
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:24:16
User entered '01 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:24:16
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:22:34
User entered '1 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 18:49:59

US3552331

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:22:34
User entered '09:35'	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:49:59

US3552331

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered '01 Oct 2020 09:35'	System	09 Nov 2020 16:24:16
User entered '1 Oct 2020 09:35'	System	01 Oct 2020 18:49:59

US3552331

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:13:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:34
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:24:23
User entered '01 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:24:23
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:22:47
User entered '1 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 18:50:11

US3552331

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:13:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:50:11

US3552331

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:13:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:22:47
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:50:11

US3552331

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:13:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:22:47
User entered '09:36'	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:50:11

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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered '01 Oct 2020 09:36'	System	09 Nov 2020 16:24:23
User entered '1 Oct 2020 09:36'	System	01 Oct 2020 18:50:11

US3552331

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:13:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Dublin (b) (4) (b) (4)	01 Oct 2020 18:50:11

US3552331

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:13:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:22:47
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:50:11

US3552331

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:13:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:22:47
User entered empty.	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 18:50:11

US3552331

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered empty.	System	01 Oct 2020 18:50:11

US3552331

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:22:54
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 16:12:52

US3552331

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered 'I'	System	08 Oct 2020 16:12:52

US3552331

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:23:00
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 16:13:00

US3552331

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:53
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:24:32
User entered '08 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:24:32
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:23:00
User entered '8 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 16:13:00

US3552331

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:23:00
User entered 'Contact Made (CONTACT MADE)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 16:13:00

US3552331

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:23:00
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 16:13:00

US3552331

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:18:11
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	15 Oct 2020 17:35:13

US3552331

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User entered 'l'	System	15 Oct 2020 17:35:13

US3552331

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:18:17
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	15 Oct 2020 17:35:22

US3552331

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:18:17
User entered '15 Oct 2020'	Stanley Doublin (b) (4) (b) (4)	15 Oct 2020 17:35:22

US3552331

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:18:17
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4) (b) (4)	15 Oct 2020 17:35:22

US3552331

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:18:17
User entered empty.	Stanley Doublin (b) (4) (b) (4)	15 Oct 2020 17:35:22

US3552331

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:18:51
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	22 Oct 2020 16:13:33

US3552331

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User entered 'l'	System	22 Oct 2020 16:13:33

US3552331

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:18:58
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	22 Oct 2020 16:13:42

US3552331

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:18:58
User entered '22 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	22 Oct 2020 16:13:42

US3552331

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:18:58
User entered 'Contact Made (CONTACT MADE)'	Mikayla Frye (b) (4) (b) (4)	22 Oct 2020 16:13:42

US3552331

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:18:58
User entered empty.	Mikayla Frye (b) (4) (b) (4)	22 Oct 2020 16:13:42

US3552331

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 14:56:18
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	29 Oct 2020 14:01:34

US3552331

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User entered 'l'	System	29 Oct 2020 14:01:34

US3552331

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 14:56:35
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	29 Oct 2020 14:01:44

US3552331

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 14:56:35
User entered '29 Oct 2020'	Stanley Doublin (b) (4) (b) (4)	29 Oct 2020 14:01:44

US3552331

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:46

[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 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 14:56:35
User entered 'Clinic (Clinic)'	Stanley Doublin (b) (4) (b) (4)	29 Oct 2020 14:01:44

US3552331

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered 'VISIT3'	System	29 Oct 2020 14:01:44

US3552331

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 14:56:42
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	29 Oct 2020 14:01:52

US3552331

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 14:56:42
User entered empty.	Stanley Doublin (b) (4) (b) (4)	29 Oct 2020 14:01:52

US3552331

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 14:56:42
User entered empty.	Stanley Doublin (b) (4) (b) (4)	29 Oct 2020 14:01:52

US3552331

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered empty.	System	29 Oct 2020 14:01:52

US3552331

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 14:56:42
User entered empty.	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 14:01:52

US3552331

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 14:56:42
User entered empty.	Stanley Doublin (b) (4) (b) (4)	29 Oct 2020 14:01:52

US3552331

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 14:56:42
User entered empty.	Stanley Doublin (b) (4) (b) (4)	29 Oct 2020 14:01:52

US3552331

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 14:56:42
User entered empty.	Stanley Doublin (b) (4) (b) (4)	29 Oct 2020 14:01:52

US3552331

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered empty.	System	29 Oct 2020 14:01:52

US3552331

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 14:56:42
User entered empty.	Stanley Doublin (b) (4) (b) (4)	29 Oct 2020 14:01:52

US3552331

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered empty.	System	29 Oct 2020 14:01:52

US3552331

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 14:56:42
User entered empty.	Stanley Doublin (b) (4) (b) (4)	29 Oct 2020 14:01:52

US3552331

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered empty.	System	29 Oct 2020 14:01:52

US3552331

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 14:56:42
User entered empty.	Stanley Doublin (b) (4) (b) (4)	29 Oct 2020 14:01:52

US3552331

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered empty.	System	29 Oct 2020 14:01:52

US3552331

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24

US3552331

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24

US3552331

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 14:56:50
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	29 Oct 2020 14:01:57

US3552331

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 14:56:50
User entered empty.	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 14:01:57

US3552331

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 14:57:21
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	29 Oct 2020 14:02:10

US3552331

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 14:57:21
User entered '29 Oct 2020'	Stanley Doublin (b) (4) (b) (4)	29 Oct 2020 14:02:10

US3552331

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 14:57:21
User entered '08:39'	Stanley Doublin (b) (4) (b) (4)	29 Oct 2020 14:02:10

US3552331

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered '29 Oct 2020 08:39'	System	29 Oct 2020 14:02:10

US3552331

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:40:45
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	23 Nov 2020 20:07:39

US3552331

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:24
User entered 'I'	System	23 Nov 2020 20:07:39

US3552331

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
Data entry locked.	System	04 Sep 2020 17:39:31
User entered 'Day 64'	System	04 Sep 2020 17:39:31

US3552331

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[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 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-11-05T23:22:57', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '55abf9e0-b01a-4263-880a-1b79a243c7a7'	System	06 Nov 2020 05:23:43
User entered 'No (N)'	System	06 Nov 2020 05:23:43

US3552331

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

Have you been exposed to someone with 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 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-11-05T23:23:33', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '55abf9e0-b01a-4263-880a-1b79a243c7a7'	System	06 Nov 2020 05:23:43
User entered 'No (N)'	System	06 Nov 2020 05:23:43

US3552331

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-11-05T23:23:40', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '55abf9e0-b01a-4263-880a-1b79a243c7a7'	System	06 Nov 2020 05:23:43
User entered '05 Nov 2020 23:23:40'	System	06 Nov 2020 05:23:43

US3552331

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
Data entry locked.	System	04 Sep 2020 17:39:31
User entered '04 Nov 2020 00:01'	System	04 Sep 2020 17:39:31

US3552331

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
Data entry locked.	System	04 Sep 2020 17:39:31
User entered '08 Nov 2020 23:59'	System	04 Sep 2020 17:39:31

US3552331

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
Data entry locked.	System	04 Sep 2020 17:39:31
User entered 'Day 71'	System	04 Sep 2020 17:39:31

US3552331

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[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 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-11-11T06:02:54', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '0857164c-4ebd-456a-a720-0e4a02b55600'	System	11 Nov 2020 12:03:11
User entered 'No (N)'	System	11 Nov 2020 12:03:11

US3552331

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

Have you been exposed to someone with 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 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-11-11T06:03:02', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '0857164c-4ebd-456a-a720-0e4a02b55600'	System	11 Nov 2020 12:03:11
User entered 'No (N)'	System	11 Nov 2020 12:03:11

US3552331

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-11-11T06:03:08', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '0857164c-4ebd-456a-a720-0e4a02b55600'	System	11 Nov 2020 12:03:11
User entered '11 Nov 2020 06:03:08'	System	11 Nov 2020 12:03:11

US3552331

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
Data entry locked.	System	04 Sep 2020 17:39:31
User entered '11 Nov 2020 00:01'	System	04 Sep 2020 17:39:31

US3552331

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
Data entry locked.	System	04 Sep 2020 17:39:31
User entered '15 Nov 2020 23:59'	System	04 Sep 2020 17:39:31

US3552331

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
Data entry locked.	System	04 Sep 2020 17:39:31
User entered 'Day 78'	System	04 Sep 2020 17:39:31

US3552331

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[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 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-11-18T05:45:21', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '17364ba3-991c-4a41-a7e6-5372115fbe1b'	System	18 Nov 2020 11:45:46
User entered 'No (N)'	System	18 Nov 2020 11:45:46

US3552331

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

Have you been exposed to someone with 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 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-11-18T05:45:36', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '17364ba3-991c-4a41-a7e6-5372115fbe1b'	System	18 Nov 2020 11:45:46
User entered 'No (N)'	System	18 Nov 2020 11:45:46

US3552331

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-11-18T05:45:42', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '17364ba3-991c-4a41-a7e6-5372115fbe1b'	System	18 Nov 2020 11:45:46
User entered '18 Nov 2020 05:45:42'	System	18 Nov 2020 11:45:46

US3552331

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
Data entry locked.	System	04 Sep 2020 17:39:31
User entered '18 Nov 2020 00:01'	System	04 Sep 2020 17:39:31

US3552331

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:16:03
Data entry locked.	System	04 Sep 2020 17:39:31
User entered '22 Nov 2020 23:59'	System	04 Sep 2020 17:39:31

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[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 (83a21207b2c45b5c)', Time: '2020-11-23T06:59:13', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '931dc678-ac6c-43b6-b0c5-d40c30039c58'	System	23 Nov 2020 12:59:45
User entered 'No (N)'	System	23 Nov 2020 12:59:45

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Have you been exposed to someone with 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 (83a21207b2c45b5c)', Time: '2020-11-23T06:59:24', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '931dc678-ac6c-43b6-b0c5-d40c30039c58'	System	23 Nov 2020 12:59:45
User entered 'No (N)'	System	23 Nov 2020 12:59:45

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-11-23T06:59:41', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '931dc678-ac6c-43b6-b0c5-d40c30039c58'	System	23 Nov 2020 12:59:45
User entered '23 Nov 2020 06:59:41'	System	23 Nov 2020 12:59:45

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[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 (83a21207b2c45b5c)', Time: '2020-11-29T12:33:23', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '759d4200-32e2-4fd2-80af-2b15a85a0f05'	System	29 Nov 2020 18:34:26
User entered 'No (N)'	System	29 Nov 2020 18:34:26

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

Have you been exposed to someone with 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 (83a21207b2c45b5c)', Time: '2020-11-29T12:34:12', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '759d4200-32e2-4fd2-80af-2b15a85a0f05'	System	29 Nov 2020 18:34:26
User entered 'No (N)'	System	29 Nov 2020 18:34:26

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-11-29T12:34:23', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '759d4200-32e2-4fd2-80af-2b15a85a0f05'	System	29 Nov 2020 18:34:26
User entered '29 Nov 2020 12:34:23'	System	29 Nov 2020 18:34:26

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[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 (83a21207b2c45b5c)', Time: '2020-12-08T06:05:42', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'a8fffee0-8d42-459e-b2ee-7d448994cb06'	System	08 Dec 2020 12:05:54
User entered 'No (N)'	System	08 Dec 2020 12:05:54

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

Have you been exposed to someone with 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 (83a21207b2c45b5c)', Time: '2020-12-08T06:05:44', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'a8fffee0-8d42-459e-b2ee-7d448994cb06'	System	08 Dec 2020 12:05:54
User entered 'No (N)'	System	08 Dec 2020 12:05:54

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-12-08T06:05:52', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'a8fffee0-8d42-459e-b2ee-7d448994cb06'	System	08 Dec 2020 12:05:54
User entered '08 Dec 2020 06:05:52'	System	08 Dec 2020 12:05:54

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[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 (83a21207b2c45b5c)', Time: '2020-12-13T00:01:38', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'cd0586f1-0e25-4b18-84b4-1aa69df91d2f'	System	13 Dec 2020 06:02:05
User entered 'No (N)'	System	13 Dec 2020 06:02:05

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

Have you been exposed to someone with 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 (83a21207b2c45b5c)', Time: '2020-12-13T00:01:44', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'cd0586f1-0e25-4b18-84b4-1aa69df91d2f'	System	13 Dec 2020 06:02:05
User entered 'No (N)'	System	13 Dec 2020 06:02:05

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-12-13T00:01:48', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'cd0586f1-0e25-4b18-84b4-1aa69df91d2f'	System	13 Dec 2020 06:02:05
User entered '13 Dec 2020 00:01:48'	System	13 Dec 2020 06:02:05

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[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 (83a21207b2c45b5c)', Time: '2020-12-20T16:29:40', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '63d36739-db89-4afe-92a9-43abe726f8f7'	System	20 Dec 2020 22:29:51
User entered 'No (N)'	System	20 Dec 2020 22:29:51

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

Have you been exposed to someone with 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 (83a21207b2c45b5c)', Time: '2020-12-20T16:29:44', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '63d36739-db89-4afe-92a9-43abe726f8f7'	System	20 Dec 2020 22:29:51
User entered 'No (N)'	System	20 Dec 2020 22:29:51

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-12-20T16:29:47', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '63d36739-db89-4afe-92a9-43abe726f8f7'	System	20 Dec 2020 22:29:51
User entered '20 Dec 2020 16:29:47'	System	20 Dec 2020 22:29:51

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[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 (83a21207b2c45b5c)', Time: '2020-12-27T07:34:32', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'e5f4d152-04b4-43b2-96c1-fa8c7ca1d4fd'	System	27 Dec 2020 13:34:47
User entered 'No (N)'	System	27 Dec 2020 13:34:47

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Have you been exposed to someone with 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 (83a21207b2c45b5c)', Time: '2020-12-27T07:34:38', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'e5f4d152-04b4-43b2-96c1-fa8c7ca1d4fd'	System	27 Dec 2020 13:34:47
User entered 'No (N)'	System	27 Dec 2020 13:34:47

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2020-12-27T07:34:41', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'e5f4d152-04b4-43b2-96c1-fa8c7ca1d4fd' User entered '27 Dec 2020 07:34:41'	System	27 Dec 2020 13:34:47

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[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 (83a21207b2c45b5c)', Time: '2021-01-04T06:55:56', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'f78f7763-28d0-41dd-8341-6522db9f30fb'	System	04 Jan 2021 12:56:07
User entered 'No (N)'	System	04 Jan 2021 12:56:07

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Have you been exposed to someone with 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 (83a21207b2c45b5c)', Time: '2021-01-04T06:56:00', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'f78f7763-28d0-41dd-8341-6522db9f30fb'	System	04 Jan 2021 12:56:07
User entered 'No (N)'	System	04 Jan 2021 12:56:07

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2021-01-04T06:56:03', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'f78f7763-28d0-41dd-8341-6522db9f30fb' User entered '04 Jan 2021 06:56:03'	System	04 Jan 2021 12:56:07

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[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 (83a21207b2c45b5c)', Time: '2021-01-14T14:53:29', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '721f8d02-4bac-4df1-9348-e3d737bab418'	System	14 Jan 2021 20:53:40
User entered 'No (N)'	System	14 Jan 2021 20:53:40

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

Have you been exposed to someone with 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 (83a21207b2c45b5c)', Time: '2021-01-14T14:53:33', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '721f8d02-4bac-4df1-9348-e3d737bab418'	System	14 Jan 2021 20:53:40
User entered 'No (N)'	System	14 Jan 2021 20:53:40

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2021-01-14T14:53:35', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '721f8d02-4bac-4df1-9348-e3d737bab418'	System	14 Jan 2021 20:53:40
User entered '14 Jan 2021 14:53:35'	System	14 Jan 2021 20:53:40

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[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 (83a21207b2c45b5c)', Time: '2021-01-17T07:13:40', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '725eeeb5-5711-4d95-a4cd-64e9e2560c09'	System	17 Jan 2021 13:13:49
User entered 'No (N)'	System	17 Jan 2021 13:13:49

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Have you been exposed to someone with 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 (83a21207b2c45b5c)', Time: '2021-01-17T07:13:43', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '725eeeb5-5711-4d95-a4cd-64e9e2560c09'	System	17 Jan 2021 13:13:49
User entered 'No (N)'	System	17 Jan 2021 13:13:49

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2021-01-17T07:13:46', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '725eeeb5-5711-4d95-a4cd-64e9e2560c09' User entered '17 Jan 2021 07:13:46'	System	17 Jan 2021 13:13:49

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[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 (83a21207b2c45b5c)', Time: '2021-01-24T06:10:41', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'c45beb50-9449-4633-9900-1e3776688723'	System	24 Jan 2021 11:10:55
User entered 'No (N)'	System	24 Jan 2021 11:10:55

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Have you been exposed to someone with 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 (83a21207b2c45b5c)', Time: '2021-01-24T06:10:47', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'c45beb50-9449-4633-9900-1e3776688723'	System	24 Jan 2021 11:10:55
User entered 'No (N)'	System	24 Jan 2021 11:10:55

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2021-01-24T06:10:51', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'c45beb50-9449-4633-9900-1e3776688723' User entered '24 Jan 2021 06:10:51'	System	24 Jan 2021 11:10:55
	System	24 Jan 2021 11:10:55

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[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 (83a21207b2c45b5c)', Time: '2021-01-31T08:12:49', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '59607efa-bcbf-4ed1-bb0e-17219482e860'	System	31 Jan 2021 13:12:57
User entered 'No (N)'	System	31 Jan 2021 13:12:57

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Have you been exposed to someone with 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 (83a21207b2c45b5c)', Time: '2021-01-31T08:12:51', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '59607efa-bcbf-4ed1-bb0e-17219482e860'	System	31 Jan 2021 13:12:57
User entered 'No (N)'	System	31 Jan 2021 13:12:57

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2021-01-31T08:12:54', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '59607efa-bcbf-4ed1-bb0e-17219482e860' User entered '31 Jan 2021 08:12:54'	System	31 Jan 2021 13:12:57

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[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 (83a21207b2c45b5c)', Time: '2021-02-08T08:36:36', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'eee527da-2f01-4ec2-a22f-f61e2f920b8b'	System	08 Feb 2021 14:36:44
User entered 'No (N)'	System	08 Feb 2021 14:36:44

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Have you been exposed to someone with 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 (83a21207b2c45b5c)', Time: '2021-02-08T08:36:38', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'ee527da-2f01-4ec2-a22f-f61e2f920b8b'	System	08 Feb 2021 14:36:44
User entered 'No (N)'	System	08 Feb 2021 14:36:44

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2021-02-08T08:36:40', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'eee527da-2f01-4ec2-a22f-f61e2f920b8b'	System	08 Feb 2021 14:36:44
User entered '08 Feb 2021 08:36:40'	System	08 Feb 2021 14:36:44

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[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 (83a21207b2c45b5c)', Time: '2021-02-14T15:45:21', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '78eae77f-371b-4ce0-a5d8-a02aed42a34b'	System	14 Feb 2021 21:45:33
User entered 'No (N)'	System	14 Feb 2021 21:45:33

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Have you been exposed to someone with 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 (83a21207b2c45b5c)', Time: '2021-02-14T15:45:23', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '78eae77f-371b-4ce0-a5d8-a02aed42a34b'	System	14 Feb 2021 21:45:33
User entered 'No (N)'	System	14 Feb 2021 21:45:33

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2021-02-14T15:45:26', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '78eae77f-371b-4ce0-a5d8-a02aed42a34b' User entered '14 Feb 2021 15:45:26'	System	14 Feb 2021 21:45:33

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[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 (83a21207b2c45b5c)', Time: '2021-02-21T06:11:01', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '939c33dc-fc09-4ecd-aaea-c13f20428d98'	System	21 Feb 2021 12:11:19
User entered 'No (N)'	System	21 Feb 2021 12:11:19

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

Have you been exposed to someone with 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 (83a21207b2c45b5c)', Time: '2021-02-21T06:11:05', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '939c33dc-fc09-4ecd-aaea-c13f20428d98'	System	21 Feb 2021 12:11:19
User entered 'No (N)'	System	21 Feb 2021 12:11:19

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2021-02-21T06:11:15', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '939c33dc-fc09-4ecd-aaea-c13f20428d98'	System	21 Feb 2021 12:11:19
User entered '21 Feb 2021 06:11:15'	System	21 Feb 2021 12:11:19

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[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 (83a21207b2c45b5c)', Time: '2021-02-28T07:42:53', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '5bfadb23-66d7-4b2f-8966-059c77ec1251'	System	28 Feb 2021 13:43:04
User entered 'No (N)'	System	28 Feb 2021 13:43:04

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

Have you been exposed to someone with 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 (83a21207b2c45b5c)', Time: '2021-02-28T07:42:58', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '5bfadb23-66d7-4b2f-8966-059c77ec1251'	System	28 Feb 2021 13:43:04
User entered 'No (N)'	System	28 Feb 2021 13:43:04

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2021-02-28T07:43:01', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '5bfadb23-66d7-4b2f-8966-059c77ec1251'	System	28 Feb 2021 13:43:04
User entered '28 Feb 2021 07:43:01'	System	28 Feb 2021 13:43:04

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[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 (83a21207b2c45b5c)', Time: '2021-03-07T16:43:01-06:00', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'b59eac13-b012-47cb-8089-cbda4f0a46bc'	System	07 Mar 2021 22:43:11
User entered 'No (N)'	System	07 Mar 2021 22:43:11

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

Have you been exposed to someone with 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 (83a21207b2c45b5c)', Time: '2021-03-07T16:43:04-06:00', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'b59eac13-b012-47cb-8089-cbda4f0a46bc' User entered 'No (N)'	System	07 Mar 2021 22:43:11

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2021-03-07T16:43:07-06:00', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'b59eac13-b012-47cb-8089-cbda4f0a46bc' User entered '07 Mar 2021 16:43:07'	System	07 Mar 2021 22:43:11
	System	07 Mar 2021 22:43:11

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[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 (83a21207b2c45b5c)', Time: '2021-03-14T23:12:52-05:00', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '6df588b8-c990-4e21-a346-caf71d66b626'	System	15 Mar 2021 04:13:04
User entered 'No (N)'	System	15 Mar 2021 04:13:04

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

Have you been exposed to someone with 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 (83a21207b2c45b5c)', Time: '2021-03-14T23:12:54-05:00', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '6df588b8-c990-4e21-a346-caf71d66b626'	System	15 Mar 2021 04:13:04
User entered 'No (N)'	System	15 Mar 2021 04:13:04

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2021-03-14T23:12:58-05:00', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '6df588b8-c990-4e21-a346-eaf71d66b626'	System	15 Mar 2021 04:13:04
User entered '14 Mar 2021 23:12:58'	System	15 Mar 2021 04:13:04

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[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 (83a21207b2c45b5c)', Time: '2021-03-21T06:02:47-05:00', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '4cddb7ff-922e-4bf5-a20c-5f569f22ad8b' User entered 'No (N)'	System	21 Mar 2021 11:03:00
	System	21 Mar 2021 11:03:00

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

Have you been exposed to someone with 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 (83a21207b2c45b5c)', Time: '2021-03-21T06:02:53-05:00', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '4cddb7ff-922e-4bf5-a20c-5f569f22ad8b'	System	21 Mar 2021 11:03:00
User entered 'No (N)'	System	21 Mar 2021 11:03:00

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2021-03-21T06:02:56-05:00', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '4cddb7ff-922e-4bf5-a20c-5f569f22ad8b' User entered '21 Mar 2021 06:02:56'	System	21 Mar 2021 11:03:00
	System	21 Mar 2021 11:03:00

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[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 (83a21207b2c45b5c)', Time: '2021-03-28T17:55:06-05:00', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '7e42f783-e148-499a-b186-06d058381840'	System	28 Mar 2021 22:55:15
User entered 'No (N)'	System	28 Mar 2021 22:55:15

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

Have you been exposed to someone with 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 (83a21207b2c45b5c)', Time: '2021-03-28T17:55:09-05:00', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '7e42f783-e148-499a-b186-06d058381840'	System	28 Mar 2021 22:55:15
User entered 'No (N)'	System	28 Mar 2021 22:55:15

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2021-03-28T17:55:11-05:00', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '7e42f783-e148-499a-b186-06d058381840'	System	28 Mar 2021 22:55:15
User entered '28 Mar 2021 17:55:11'	System	28 Mar 2021 22:55:15

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[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 (83a21207b2c45b5c)', Time: '2021-04-04T10:38:55-05:00', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '97d2901d-db70-40fc-b053-55554966bcd' User entered 'No (N)'	System	04 Apr 2021 15:39:03

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Have you been exposed to someone with 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 (83a21207b2c45b5c)', Time: '2021-04-04T10:38:57-05:00', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '97d2901d-db70-40fc-b053-55554966bcd'	System	04 Apr 2021 15:39:03
User entered 'No (N)'	System	04 Apr 2021 15:39:03

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2021-04-04T10:39:00-05:00', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '97d2901d-db70-40fc-b053-55554966bcd b'	System	04 Apr 2021 15:39:03
User entered '04 Apr 2021 10:39:00'	System	04 Apr 2021 15:39:03

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[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 (83a21207b2c45b5c)', Time: '2021-04-11T06:36:33-05:00', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '6b94d6e7-2484-44dc-8b0a-6154ca6b8baf' User entered 'No (N)'	System	11 Apr 2021 11:36:43
	System	11 Apr 2021 11:36:43

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

Have you been exposed to someone with 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 (83a21207b2c45b5c)', Time: '2021-04-11T06:36:36-05:00', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '6b94d6e7-2484-44dc-8b0a-6154ca6b8baf' User entered 'No (N)'	System	11 Apr 2021 11:36:43

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2021-04-11T06:36:40-05:00', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '6b94d6e7-2484-44dc-8b0a-6154ca6b8baf' User entered '11 Apr 2021 06:36:40'	System	11 Apr 2021 11:36:43
	System	11 Apr 2021 11:36:43

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[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 (83a21207b2c45b5c)', Time: '2021-04-18T01:09:30-05:00', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '8089772b-e216-478f-bdc5-c2c26d436ab0' User entered 'No (N)'	System	18 Apr 2021 06:09:43
	System	18 Apr 2021 06:09:43

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

Have you been exposed to someone with 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 (83a21207b2c45b5c)', Time: '2021-04-18T01:09:34-05:00', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '8089772b-e216-478f-bdc5-c2c26d436ab0'	System	18 Apr 2021 06:09:43
User entered 'No (N)'	System	18 Apr 2021 06:09:43

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2021-04-18T01:09:39-05:00', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '8089772b-e216-478f-bdc5-c2c26d436ab0' User entered '18 Apr 2021 01:09:39'	System	18 Apr 2021 06:09:43
	System	18 Apr 2021 06:09:43

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[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 (83a21207b2c45b5c)', Time: '2021-04-25T00:05:52-05:00', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '99d979b4-b287-46b0-b265-27b98e552d63'	System	25 Apr 2021 05:06:41
User entered 'No (N)'	System	25 Apr 2021 05:06:41

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

Have you been exposed to someone with 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 (83a21207b2c45b5c)', Time: '2021-04-25T00:05:54-05:00', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '99d979b4-b287-46b0-b265-27b98e552d63'	System	25 Apr 2021 05:06:41
User entered 'No (N)'	System	25 Apr 2021 05:06:41

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2021-04-25T00:05:57-05:00', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '99d979b4-b287-46b0-b265-27b98e552d63'	System	25 Apr 2021 05:06:41
User entered '25 Apr 2021 00:05:57'	System	25 Apr 2021 05:06:41

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[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 (83a21207b2c45b5c)', Time: '2021-05-02T01:09:34-04:00', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '4805b318-6507-425d-9ae3-275bfe7aefbb'	System	02 May 2021 05:09:53
User entered 'No (N)'	System	02 May 2021 05:09:53

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Have you been exposed to someone with 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 (83a21207b2c45b5c)', Time: '2021-05-02T01:09:47-04:00', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '4805b318-6507-425d-9ae3-275bfe7aefbb'	System	02 May 2021 05:09:53
User entered 'No (N)'	System	02 May 2021 05:09:53

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2021-05-02T01:09:50-04:00', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: '4805b318-6507-425d-9ae3-275bfe7aefbb'	System	02 May 2021 05:09:53
User entered '02 May 2021 01:09:50'	System	02 May 2021 05:09:53

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 03:58:35

US3552331

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:58:35
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 03:58:35

US3552331

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:13:46

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 11:28:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2021-02-28T07:43:12', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'bb6a1e81-8858-41dd-9d65-74bd725a195c'	System	28 Feb 2021 13:43:20
User entered 'No (N)'	System	28 Feb 2021 13:43:20

US3552331

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:13:46

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:28:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83a21207b2c45b5c)', Time: '2021-02-28T07:43:17', User OID: 'PatientReportedOutcome (US3552331)', ODM File OID: 'bb6a1e81-8858-41dd-9d65-74bd725a195c'	System	28 Feb 2021 13:43:20
User entered '28 Feb 2021 07:43:17'	System	28 Feb 2021 13:43:20

US3552331

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:40:51
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	23 Nov 2020 20:07:48

US3552331

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:40:51
User entered '23 Nov 2020'	Stanley Doublin (b) (4) (b) (4)	23 Nov 2020 20:07:48

US3552331

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:40:51
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4) (b) (4)	23 Nov 2020 20:07:48

US3552331

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:40:51
User entered empty.	Stanley Dublin (b) (4) (b) (4)	23 Nov 2020 20:07:48

US3552331

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:33:45
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	29 Dec 2020 16:35:35

US3552331

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 10:36:22
User entered 'l'	System	29 Dec 2020 16:35:35

US3552331

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:33:51
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	29 Dec 2020 16:35:43

US3552331

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 16:33:51
User entered '29 Dec 2020'	Mikayla Frye (b) (4)	29 Dec 2020 16:35:43
	(b) (4)	

US3552331

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 16:33:51
User entered 'Contact Made (CONTACT MADE)'	Mikayla Frye (b) (4)	29 Dec 2020 16:35:43
	(b) (4)	

US3552331

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	04 Feb 2021 16:33:51
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 16:33:51
	Mikayla Frye (b) (4)	29 Dec 2020 16:35:43
	(b) (4)	

US3552331

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:33:59
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	29 Jan 2021 15:47:48

US3552331

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
User entered 'l'	System	29 Jan 2021 15:47:48

US3552331

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:34:04
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	29 Jan 2021 15:47:58

US3552331

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 16:34:04
User entered '29 Jan 2021'	Stanley Doublin (b) (4)	29 Jan 2021 15:47:58
	(b) (4)	

US3552331

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:34:04
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4)	29 Jan 2021 15:47:58

US3552331

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 16:34:04
User entered empty.	Stanley Doublin (b) (4)	29 Jan 2021 15:47:58
	(b) (4)	

US3552331

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
DataPoint Verified.		02 Mar 2021 16:48:42
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	11 Feb 2021 22:52:58

US3552331

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
User entered 'l'	System	11 Feb 2021 22:52:58

US3552331

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
DataPoint Verified.		02 Mar 2021 16:48:52
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:55:45
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 16:49:16

US3552331

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
DataPoint Verified.		02 Mar 2021 16:48:52
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:55:45
User entered '26 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 16:49:16

US3552331

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
DataPoint Verified.		02 Mar 2021 16:48:52
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:55:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 16:49:16

US3552331

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
DataPoint Verified.		02 Mar 2021 16:48:52
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:55:45
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 16:49:16

US3552331

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
DataPoint Verified.		02 Mar 2021 16:48:55
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:55:45
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 16:49:24

US3552331

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
User entered 'l'	System	26 Feb 2021 16:49:24

US3552331

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
DataPoint Verified.		30 Mar 2021 17:35:51
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 14:12:02

US3552331

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
DataPoint Verified.		30 Mar 2021 17:35:51
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered '29 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 14:12:02

US3552331

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
DataPoint Verified.		30 Mar 2021 17:35:51
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 14:12:02

US3552331

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
User entered 'VISIT4'	System	29 Mar 2021 14:12:02

US3552331

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
DataPoint Verified.		30 Mar 2021 17:35:56
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 14:12:06

US3552331

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
DataPoint Verified.		30 Mar 2021 17:35:56
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 14:12:06

US3552331

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
DataPoint Verified.		30 Mar 2021 17:35:56
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 14:12:06

US3552331

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
User entered empty.	System	29 Mar 2021 14:12:06

US3552331

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
DataPoint Verified.		30 Mar 2021 17:35:56
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 14:12:06

US3552331

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
DataPoint Verified.		30 Mar 2021 17:35:56
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 14:12:06

US3552331

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
DataPoint Verified.		30 Mar 2021 17:35:56
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 14:12:06

US3552331

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
DataPoint Verified.		30 Mar 2021 17:35:56
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 14:12:06

US3552331

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
User entered empty.	System	29 Mar 2021 14:12:06

US3552331

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
DataPoint Verified.		30 Mar 2021 17:35:56
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 14:12:06

US3552331

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
User entered empty.	System	29 Mar 2021 14:12:06

US3552331

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
DataPoint Verified.		30 Mar 2021 17:35:56
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 14:12:06

US3552331

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
User entered empty.	System	29 Mar 2021 14:12:06

US3552331

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
DataPoint Verified.		30 Mar 2021 17:35:56
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 14:12:06

US3552331

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
User entered empty.	System	29 Mar 2021 14:12:06

US3552331

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38

US3552331

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38

US3552331

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
DataPoint Verified.		30 Mar 2021 17:36:07
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 14:12:09

US3552331

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
DataPoint Verified.		30 Mar 2021 17:36:07
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 14:12:09

US3552331

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:36:13
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 14:12:17

US3552331

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
DataPoint Verified.		30 Mar 2021 17:36:13
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered '29 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 14:12:17

US3552331

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
DataPoint Verified.		30 Mar 2021 17:36:13
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered '08:13'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 14:12:17

US3552331

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
User entered '29 Mar 2021 08:13'	System	29 Mar 2021 14:12:17

US3552331

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
DataPoint Verified.		30 Mar 2021 17:36:41
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 14:12:21

US3552331

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:50:38
User entered 'I'	System	29 Mar 2021 14:12:21

US3552331

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

Form: Visit Date

Generated On: 10 Jun 2021 08:13:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	04 Feb 2021 16:38:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 16:38:34
	Stanley Doublin (b) (4)	02 Feb 2021 15:51:33
	(b) (4)	

US3552331

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

Form: Visit Date

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:38:34
User entered '02 Feb 2021'	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:51:33

US3552331

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

Form: Visit Date

Generated On: 10 Jun 2021 08:13:46

[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 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:38:34
User entered 'Clinic (Clinic)'	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:51:33

US3552331

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

Form: Visit Date

Generated On: 10 Jun 2021 08:13:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User entered 'UNBLND_DECIDE'	System	02 Feb 2021 15:51:33

US3552331

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

Form: Unblinding

Generated On: 10 Jun 2021 08:13:46

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:39:25
User entered '02 Feb 2021'	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:51:49

US3552331

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

Form: Unblinding

Generated On: 10 Jun 2021 08:13:46

[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 20:18:19
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:36:43
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:38:38

US3552331

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

Form: Unblinding

Generated On: 10 Jun 2021 08:13:46

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:39:25
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:51:49

US3552331

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

Form: Unblinding

Generated On: 10 Jun 2021 08:13:46

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:36:43
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 18:38:38

US3552331

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

Form: Unblinding

Generated On: 10 Jun 2021 08:13:46

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:39:25
User entered '02 Feb 2021'	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:51:49

US3552331

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

Form: Unblinding

Generated On: 10 Jun 2021 08:13:46

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:39:25
User entered 'Placebo (Placebo)'	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:51:49

US3552331

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

Form: Unblinding

Generated On: 10 Jun 2021 08:13:46

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:39:25
User entered 'Placebo (Placebo)'	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:51:49

US3552331

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

Form: Unblinding

Generated On: 10 Jun 2021 08:13:46

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:39:25
User entered 'Not Administered (NA)' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:55:51
User entered 'Placebo (Placebo)'	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:51:49

US3552331

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

Form: Unblinding

Generated On: 10 Jun 2021 08:13:46

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	04 Feb 2021 16:39:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 16:39:25
	Stanley Doublin (b) (4)	02 Feb 2021 15:51:49
	(b) (4)	

US3552331

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

Form: Unblinding

Generated On: 10 Jun 2021 08:13:46

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User entered 'I'	System	02 Feb 2021 15:51:49

US3552331

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

Form: Unblinding

Generated On: 10 Jun 2021 08:13:46

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User entered 'I'	System	02 Feb 2021 15:51:49

US3552331

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:13:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:59:13
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:53:34

US3552331

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:13:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:59:13
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	02 Feb 2021 15:53:34

US3552331

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:13:46

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User entered empty.	System	02 Feb 2021 15:53:34
DataPoint set to visible.	System	02 Feb 2021 15:51:49

US3552331

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:13:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:59:13
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:53:34

US3552331

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:13:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	04 Feb 2021 16:59:13
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Feb 2021 16:59:13
	Stanley Doublin (b) (4)	02 Feb 2021 15:53:34
	(b) (4)	

US3552331

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:13:46

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User entered empty.	System	02 Feb 2021 15:53:34
DataPoint set to visible.	System	02 Feb 2021 15:51:49

US3552331

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:53:34

US3552331

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:59:13
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:53:34

US3552331

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	04 Feb 2021 16:59:13
User entered '02 Feb 2021'	(b) (4), (b) (6)	04 Feb 2021 16:59:13
	Stanley Doublin (b) (4)	02 Feb 2021 15:53:34
	(b) (4)	

US3552331

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	04 Feb 2021 16:59:13
User entered '08:34'	(b) (4), (b) (6)	04 Feb 2021 16:59:13
	Stanley Doublin (b) (4)	02 Feb 2021 15:53:34
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User entered '02 Feb 2021 08:34'	System	02 Feb 2021 15:53:34

US3552331

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:59:13
User entered '98.1' F	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:53:34

US3552331

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:59:13
User entered 'Oral (Oral)'	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:53:34

US3552331

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:59:13
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:53:34

US3552331

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:59:13
User entered '79'	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:53:34

US3552331

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User entered 'bpm'	System	02 Feb 2021 15:53:34

US3552331

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:59:13
User entered '16'	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:53:34

US3552331

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User entered 'breaths/min'	System	02 Feb 2021 15:53:34

US3552331

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:59:13
User entered '111'	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:53:34

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User entered 'mmHg'	System	02 Feb 2021 15:53:34

US3552331

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:59:13
User entered '70'	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:53:34

US3552331

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User entered 'mmHg'	System	02 Feb 2021 15:53:34

US3552331

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:13:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	04 Feb 2021 16:59:13
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Feb 2021 16:59:13
	Stanley Doublin (b) (4)	02 Feb 2021 15:53:34
	(b) (4)	

US3552331

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:13:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:59:13
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	02 Feb 2021 15:53:34

US3552331

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:13:46

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User entered empty.	System	02 Feb 2021 15:53:34
DataPoint set to visible.	System	02 Feb 2021 15:51:49

US3552331

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:54:03

US3552331

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:59:13
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:54:03

US3552331

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:59:13
User entered '02 Feb 2021'	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:54:03

US3552331

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	04 Feb 2021 16:59:13
User entered '09:38'	(b) (4), (b) (6)	04 Feb 2021 16:59:13
	Stanley Doublin (b) (4)	02 Feb 2021 15:54:03
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User entered '02 Feb 2021 09:38'	System	02 Feb 2021 15:54:03

US3552331

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:59:13
User entered '98.5' F	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:54:03

US3552331

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:59:13
User entered 'Oral (Oral)'	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:54:03

US3552331

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	04 Feb 2021 16:59:13
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 16:59:13
	Stanley Doublin (b) (4)	02 Feb 2021 15:54:03
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:59:13
User entered '77'	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:54:03

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User entered 'bpm'	System	02 Feb 2021 15:54:03

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:59:13
User entered '16'	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:54:03

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User entered 'breaths/min'	System	02 Feb 2021 15:54:03

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	04 Feb 2021 16:59:13
User entered '99'	(b) (4), (b) (6)	04 Feb 2021 16:59:13
	Stanley Doublin (b) (4)	02 Feb 2021 15:54:03
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User entered 'mmHg'	System	02 Feb 2021 15:54:03

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	04 Feb 2021 16:59:13
User entered '68'	(b) (4), (b) (6)	04 Feb 2021 16:59:13
	Stanley Doublin (b) (4)	02 Feb 2021 15:54:03
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User entered 'mmHg'	System	02 Feb 2021 15:54:03

US3552331

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

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	04 Feb 2021 16:59:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 16:59:23
	Stanley Doublin (b) (4)	02 Feb 2021 15:52:03
	(b) (4)	

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

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:59:23
User entered '02 Feb 2021'	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:52:03

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:59:31
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:52:24

US3552331

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	04 Feb 2021 16:59:31
User entered '02 Feb 2021'	(b) (4), (b) (6)	04 Feb 2021 16:59:31
	Stanley Doublin (b) (4)	02 Feb 2021 15:52:24
	(b) (4)	

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:59:31
User entered 'Urine (URINE)'	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:52:24

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	04 Feb 2021 16:59:31
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	04 Feb 2021 16:59:31
	Stanley Doublin (b) (4)	02 Feb 2021 15:52:24
	(b) (4)	

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:59:31
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:52:24

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 19:22:40
User closed query 'FSH not collected, please remove collection time and date from two lines below. ' (Site from CRA).		09 Feb 2021 19:22:38
Query 'FSH not collected, please remove collection time and date from two lines below. ' answered with 'updated thank you!' (Site from CRA).	Cassandra Zehenny (b) (4) (b) (4)	04 Feb 2021 22:19:20
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	04 Feb 2021 22:19:14
User opened query 'FSH not collected, please remove collection time and date from two lines below. ' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 17:00:14
DataPoint Un-verified.		04 Feb 2021 16:59:38
DataPoint Verified.		04 Feb 2021 16:59:31
User entered '02 Feb 2021'	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:52:24

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	09 Feb 2021 19:22:44
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 19:22:44
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	04 Feb 2021 22:19:14
DataPoint Verified.	(b) (4)	04 Feb 2021 16:59:40
User entered '08:45'	(b) (4), (b) (6)	04 Feb 2021 16:59:40
		04 Feb 2021 16:59:31
	Stanley Dublin (b) (4)	02 Feb 2021 15:52:24
	(b) (4)	

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User entered empty.	System	04 Feb 2021 22:19:14
User entered '02 Feb 2021 08:45'	System	02 Feb 2021 15:52:24

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

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 17:00:25
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:53:03

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

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 17:00:25
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:53:03

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

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

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 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 17:00:25
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Feb 2021 15:53:03

US3552331

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

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User entered 'mRNA-1273'	System	02 Feb 2021 15:53:03
DataPoint set to visible.	System	02 Feb 2021 15:51:49

US3552331

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

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	04 Feb 2021 17:00:25
User entered '02 Feb 2021'	(b) (4), (b) (6)	04 Feb 2021 17:00:25
	Stanley Doublin (b) (4)	02 Feb 2021 15:53:03
	(b) (4)	

US3552331

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

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	04 Feb 2021 17:00:25
User entered '09:08'	(b) (4), (b) (6)	04 Feb 2021 17:00:25
	Stanley Doublin (b) (4)	02 Feb 2021 15:53:03
	(b) (4)	

US3552331

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

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User entered '02 Feb 2021 09:08'	System	02 Feb 2021 15:53:03

US3552331

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

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 17:00:25
User entered 'Left Arm (LEFT ARM)'	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:53:03

US3552331

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

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
DataPoint Verified.		04 Feb 2021 17:00:25
User entered 'ONCE'	System	02 Feb 2021 15:53:03

US3552331

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

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User entered 'INTRAMUSCULAR'	System	02 Feb 2021 15:53:03

US3552331

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 17:00:34
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:54:18

US3552331

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 17:00:34
User entered '02 Feb 2021'	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:54:18

US3552331

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 17:00:34
User entered '08:22'	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:54:18

US3552331

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User entered '02 Feb 2021 08:22'	System	02 Feb 2021 15:54:18

US3552331

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:13:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 17:00:43
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:54:29

US3552331

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:13:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	04 Feb 2021 17:00:43
User entered '02 Feb 2021'	(b) (4), (b) (6)	04 Feb 2021 17:00:43
	Stanley Doublin (b) (4)	02 Feb 2021 15:54:29
	(b) (4)	

US3552331

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 17:00:43
User entered '08:25'	Stanley Doublin (b) (4) (b) (4)	02 Feb 2021 15:54:29

US3552331

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User entered '02 Feb 2021 08:25'	System	02 Feb 2021 15:54:29

US3552331

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

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
DataPoint Verified.		15 Mar 2021 16:21:41
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	09 Feb 2021 17:02:40

US3552331

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

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:19
User entered 'I'	System	09 Feb 2021 17:02:40

US3552331

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		02 Mar 2021 17:03:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	09 Feb 2021 17:02:50

US3552331

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		02 Mar 2021 17:03:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
User entered '09 Feb 2021'	(b) (4) Mikayla Frye (b) (4) (b) (4)	09 Feb 2021 17:02:50

US3552331

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		02 Mar 2021 17:03:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	09 Feb 2021 17:02:50

US3552331

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		02 Mar 2021 17:03:09
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	09 Feb 2021 17:02:50

US3552331

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		02 Mar 2021 17:03:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	11 Feb 2021 22:53:04

US3552331

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
User entered 'l'	System	11 Feb 2021 22:53:04

US3552331

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
User entered 'I'	System	11 Feb 2021 22:53:04
DataPoint set to visible.	System	11 Feb 2021 22:53:04

US3552331

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:23:10
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:45:04

US3552331

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:23:10
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered '03 Mar 2021'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:45:04

US3552331

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:23:10
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered 'Clinic (Clinic)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:45:04

US3552331

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
User entered 'OLD29'	System	03 Mar 2021 21:45:04

US3552331

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
User accepted default value 'Pre-Dose (PREDOSE)'	Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:46:43

US3552331

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:23:39
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:46:43

US3552331

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:23:39
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered '03 Mar 2021'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:46:43

US3552331

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:23:39
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered '14:21'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:46:43

US3552331

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
User entered '03 Mar 2021 14:21'	System	03 Mar 2021 21:46:43

US3552331

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:23:39
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered '96.8' F	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:46:43

US3552331

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:23:39
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered 'Oral (Oral)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:46:43

US3552331

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:23:39
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:46:43

US3552331

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:23:39
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered '86'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:46:43

US3552331

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
User entered 'bpm'	System	03 Mar 2021 21:46:43

US3552331

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:23:39
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered '16'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:46:43

US3552331

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
User entered 'breaths/min'	System	03 Mar 2021 21:46:43

US3552331

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:23:39
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered '117'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:46:43

US3552331

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
User entered 'mmHg'	System	03 Mar 2021 21:46:43

US3552331

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:23:39
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered '79'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:46:43

US3552331

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
User entered 'mmHg'	System	03 Mar 2021 21:46:43

US3552331

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
User accepted default value 'Post-Dose (POSTDOSE)'	Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:46:43

US3552331

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:23:39
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:46:43

US3552331

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:23:39
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered '03 Mar 2021'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:46:43

US3552331

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:23:39
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered '15:16'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:46:43

US3552331

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
User entered '03 Mar 2021 15:16'	System	03 Mar 2021 21:46:43

US3552331

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:23:39
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered '97.2' F	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:46:43

US3552331

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:23:39
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered 'Oral (Oral)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:46:43

US3552331

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:23:39
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:46:43

US3552331

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:23:39
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered '86'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:46:43

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
User entered 'bpm'	System	03 Mar 2021 21:46:43

US3552331

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 16:23:39
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered '14'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:46:43

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
User entered 'breaths/min'	System	03 Mar 2021 21:46:43

US3552331

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:23:39
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered '110'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:46:43

US3552331

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
User entered 'mmHg'	System	03 Mar 2021 21:46:43

US3552331

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:23:39
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered '73'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:46:43

US3552331

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
User entered 'mmHg'	System	03 Mar 2021 21:46:43

US3552331

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:23:43
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:46:54

US3552331

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:23:43
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered '03 Mar 2021'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:46:54

US3552331

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 16:23:47
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:47:10

US3552331

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:23:47
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered '03 Mar 2021'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:47:10

US3552331

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:23:47
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered 'Urine (URINE)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:47:10

US3552331

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:23:47
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered 'Negative (NEGATIVE)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:47:10

US3552331

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:23:47
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered 'No (N)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:47:10

US3552331

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:23:47
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:47:10

US3552331

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:23:47
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:47:10

US3552331

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
User entered empty.	System	03 Mar 2021 21:47:10

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:24:01
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:47:26

US3552331

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:24:01
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:47:26

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

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)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:24:01
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:47:26

US3552331

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
User entered 'mRNA-1273'	System	03 Mar 2021 21:47:26
DataPoint set to visible.	System	11 Feb 2021 22:53:04

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:24:01
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered '03 Mar 2021'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:47:26

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:24:01
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered '14:46'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:47:26

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
User entered '03 Mar 2021 14:46'	System	03 Mar 2021 21:47:26

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:24:01
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered 'Left Arm (LEFT ARM)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:47:26

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:24:01
User entered 'ONCE'	System	03 Mar 2021 21:47:26

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:46

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
User entered 'INTRAMUSCULAR'	System	03 Mar 2021 21:47:26

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Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
DataPoint Verified.		15 Mar 2021 16:24:06
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:59:35
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	03 Mar 2021 21:47:30

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Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
User entered 'l'	System	03 Mar 2021 21:47:30

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:36:43
DataPoint Verified.	(b) (4)	15 Mar 2021 16:24:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Mar 2021 16:24:38
	Stanley Doublin (b) (4)	10 Mar 2021 19:20:53
	(b) (4)	

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:36:43
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 16:24:38
User entered '10 Mar 2021'	Stanley Dublin (b) (4)	10 Mar 2021 19:20:53

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:36:43
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 16:24:38
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4)	10 Mar 2021 19:20:53

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:36:43
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 16:24:38
User entered empty.	Stanley Doublin (b) (4)	10 Mar 2021 19:20:53

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Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:36:43
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 16:24:56
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	10 Mar 2021 19:21:40

US3552331

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:34:04
User entered 'l'	System	10 Mar 2021 19:21:40

US3552331

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:37:02
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 14:11:38

US3552331

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:37:02
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered '29 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 14:11:38

US3552331

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:37:02
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 14:11:38

US3552331

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:46

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	29 Mar 2021 14:11:38

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:37:07
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 14:11:42

US3552331

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:37:07
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 14:11:42

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:37:07
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 14:11:42

US3552331

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 14:11:42

US3552331

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:37:07
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 14:11:42

US3552331

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:37:07
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 14:11:42

US3552331

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:37:07
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 14:11:42

US3552331

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:37:07
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 14:11:42

US3552331

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 14:11:42

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:37:07
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 14:11:42

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 14:11:42

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:37:07
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 14:11:42

US3552331

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 14:11:42

US3552331

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:37:07
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Mar 2021 14:11:42

US3552331

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 14:11:42

US3552331

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:37:13
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 14:11:45

US3552331

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:46

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:37:13
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 14:11:45

US3552331

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:37:19
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 14:11:53

US3552331

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:37:19
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered '29 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 14:11:53

US3552331

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:37:19
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:30:28
User entered '08:13'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Mar 2021 14:11:53

US3552331

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
User entered '29 Mar 2021 08:13'	System	29 Mar 2021 14:11:53

US3552331

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:13:46

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:35:15
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 15:59:34
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	21 Sep 2020 19:11:43

US3552331

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:59:24
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:13
User entered	System	22 Sep 2020 14:03:08
'USA-US089-2020-mRNA-1273-P301000004'		
User entered 'New'	(b) (4), (b) (6)	22 Sep 2020 14:03:08

US3552331

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:59:24
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression worsened - version MedDRA\23.0.	Coder Import (b) (4)	01 Oct 2020 18:47:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	01 Oct 2020 18:47:49
Data point term sent to Coder	System	01 Oct 2020 18:46:34
Coding entries removed.	Stanley Doublin (b) (4)	01 Oct 2020 18:46:06
	(b) (4)	
User entered 'worsening DEPRESSION' reason for change: Data Entry Error	Stanley Doublin (b) (4)	01 Oct 2020 18:46:06
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\23.0.	Coder Import (b) (4)	21 Sep 2020 19:19:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Sep 2020 19:19:42
Data point term sent to Coder	System	21 Sep 2020 19:18:49
User entered 'depression'	Joan Siegner (b) (4)	21 Sep 2020 19:18:34

US3552331

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:59:24
User entered 'Yes (Y)'	Joan Siegner (b) (4)	21 Sep 2020 19:18:34

US3552331

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:59:24
User entered 'No (N)'	Joan Siegner (b) (4)	21 Sep 2020 19:18:34

US3552331

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 15:59:24
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 19:18:34
	Joan Siegner (b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:51:55
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	28 Jan 2021 20:18:29
	(b) (4)	
User entered '14 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Jan 2021 20:18:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 15:59:24
User entered '15 Sep 2020'	Joan Siegner (b) (4)	21 Sep 2020 19:18:34

US3552331

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:59:24
User entered empty.	Joan Siegner (b) (4)	21 Sep 2020 19:18:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 19:18:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:59:24
User entered 'No (N)' reason for change: Data Entry Error	Stanley Dublin (b) (4)	01 Oct 2020 18:44:36
User entered 'Yes (Y)'	Joan Siegner (b) (4)	21 Sep 2020 19:18:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 20:30:37
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	09 Nov 2020 16:25:23
User entered '01 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	09 Nov 2020 16:25:23
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 15:59:24
User entered '1 Oct 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4)	01 Oct 2020 18:44:36
	(b) (4)	
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 15:13:55
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'unknown at this time' (Site from Safety).	Joan Siegner (b) (4)	30 Sep 2020 17:51:31
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 14:41:59
User entered empty.	Joan Siegner (b) (4)	21 Sep 2020 19:18:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 15:59:24
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 19:18:34
	Joan Siegner (b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 19:18:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	27 Oct 2020 20:16:30
User closed query 'Please verify grading. Hospitalization suggests Grade 4. ' (Site from CRA). Query 'Please verify grading. Hospitalization suggests Grade 4. ' answered with 'Data entered by accident 3 instead of 4' (Site from CRA). User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error User opened query 'Please verify grading. Hospitalization suggests Grade 4. ' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 20:16:29 26 Oct 2020 15:41:33 26 Oct 2020 15:41:02 25 Oct 2020 02:20:04 25 Oct 2020 02:19:27
DataPoint Verified.		12 Oct 2020 15:59:24
User entered 'Grade 3/Severe (Grade 3/Severe)'	Joan Siegner (b) (4)	21 Sep 2020 19:18:34

US3552331

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 15:59:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 19:18:34
	Joan Siegner (b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:59:24
User entered '0'	Joan Siegner (b) (4)	21 Sep 2020 19:18:34

US3552331

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:59:24
User entered '0'	Joan Siegner (b) (4)	21 Sep 2020 19:18:34

US3552331

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 15:59:24
User closed query 'Please update this SAE per PCP provider records on 28Sep2020.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 01:01:24
Query 'Please update this SAE per PCP provider records on 28Sep2020.' answered with 'done' (Site from CRA).	Joan Siegner (b) (4)	30 Sep 2020 17:51:37
User opened query 'Please update this SAE per PCP provider records on 28Sep2020.' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 16:35:31
User closed 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	28 Sep 2020 15:24:59
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.' answered by data change (Site from System).	System	28 Sep 2020 15:24:59
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	28 Sep 2020 15:24:37
User closed 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).	(b) (4), (b) (6)	24 Sep 2020 06:54:33
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.' answered with 'data is unknown at this time.' (Site from System).	Joan Siegner (b) (4)	21 Sep 2020 19:19:28

US3552331

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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). User entered 'I'	System	21 Sep 2020 19:18:34
	Joan Siegner (b) (4) [REDACTED]	21 Sep 2020 19:18:34

US3552331

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:59:24
User entered '16 Sep 2020' reason for change: Data Entry Error	Joan Siegner (b) (4)	28 Sep 2020 15:24:37
User entered '15 Sep 2020'	Joan Siegner (b) (4)	21 Sep 2020 19:18:34

US3552331

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 15:59:24
	(b) (4), (b) (6)	
User entered '21 Sep 2020' reason for change: Data Entry Error	Joan Siegner (b) (4)	28 Sep 2020 15:24:59
User entered empty.	Joan Siegner (b) (4)	21 Sep 2020 19:18:34

US3552331

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:59:24
User entered 'No (N)'	Joan Siegner (b) (4) [REDACTED]	21 Sep 2020 19:18:34

US3552331

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:59:24
User entered empty.	Joan Siegner (b) (4)	21 Sep 2020 19:18:34

US3552331

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:59:24
User entered '0'	Joan Siegner (b) (4)	21 Sep 2020 19:18:34

US3552331

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:59:24
User entered '0'	Joan Siegner (b) (4)	21 Sep 2020 19:18:34

US3552331

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:59:24
User entered '0'	Joan Siegner (b) (4)	21 Sep 2020 19:18:34

US3552331

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:59:24
User entered 'Not Related (NOT RELATED)'	Joan Siegner (b) (4)	21 Sep 2020 19:18:34

US3552331

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:59:24
User entered 'Not Related (NOT RELATED)'	Joan Siegner (b) (4)	21 Sep 2020 19:18:34

US3552331

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	25 Oct 2020 02:20:34
User closed query 'Per source, second dose is not administered due to this SAE. Please consider updating to" Investigational product withdrawn". ' (Site from CRA).	(b) (4), (b) (6)	13 Oct 2020 16:48:37
Query 'Per source, second dose is not administered due to this SAE. Please consider updating to" Investigational product withdrawn". ' answered with 'updated' (Site from CRA).	Heather Douds (b) (4)	12 Oct 2020 19:31:59
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Per Query Resolution	(b) (4)	12 Oct 2020 19:31:53
User opened query 'Per source, second dose is not administered due to this SAE. Please consider updating to" Investigational product withdrawn". ' (Site from CRA).	(b) (4), (b) (6)	12 Oct 2020 16:21:24
DataPoint Un-verified.		12 Oct 2020 16:18:49
DataPoint Verified.		12 Oct 2020 15:59:24
User entered 'None (NONE)'	Joan Siegner (b) (4)	21 Sep 2020 19:18:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:59:24
User entered '0'	Joan Siegner (b) (4)	21 Sep 2020 19:18:34

US3552331

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 15:59:24
User entered 'l'	(b) (4), (b) (6)	
	Joan Siegner (b) (4)	21 Sep 2020 19:18:34

US3552331

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 15:59:24
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 15:59:24
	Joan Siegner (b) (4)	21 Sep 2020 19:18:34

US3552331

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:59:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Stanley Dublin (b) (4)	01 Oct 2020 18:44:36
Data Entry Error	(b) (4)	
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 15:14:03
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'not available at this time' (Site from Safety).	Joan Siegner (b) (4)	30 Sep 2020 17:51:50
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 14:42:46
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Joan Siegner (b) (4)	21 Sep 2020 19:18:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

[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 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 15:59:24
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 15:59:24
	Joan Siegner (b) (4)	21 Sep 2020 19:18:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
User closed query 'Per DM CLR: SAE Narrative = SUBJECT TOOK 5 TRAZADONE IN ATTEMPT TO SLEEP. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Dec 2020 05:24:01
Query 'Per DM CLR: SAE Narrative = SUBJECT TOOK 5 TRAZADONE IN ATTEMPT TO SLEEP. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Con Med #8' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	29 Dec 2020 22:48:31
User opened query 'Per DM CLR: SAE Narrative = SUBJECT TOOK 5 TRAZADONE IN ATTEMPT TO SLEEP. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	26 Dec 2020 21:53:20
User closed query 'Per DM CLR: Narrative indicates that the subject took 5 Trazodone. However, there is no corresponding ConMed record that match this information. Please update to record the corresponding ConMed as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 11:47:57
Query 'Per DM CLR: Narrative indicates that the subject took 5 Trazodone. However, there is no corresponding ConMed record that match this information. Please update to record the corresponding ConMed as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	16 Nov 2020 15:54:12
User opened query 'Per DM CLR: Narrative indicates that the subject took 5 Trazodone. However, there is no corresponding ConMed record that match this information. Please update to record the corresponding ConMed as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	15 Nov 2020 12:56:08
User closed query 'PV query: What was the dosage prescribed to the subject for trazadone?' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 12:24:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV query: What was the dosage prescribed to the subject for trazadone?' answered with 'dosage unknown' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 15:42:26
User opened query 'PV query: What was the dosage prescribed to the subject for trazadone?' (Site from Safety).		22 Oct 2020 15:34:33
User closed query 'PV query: What was the dosage prescribed to the subject for trazadone?' (Site from Safety).		19 Oct 2020 19:46:10
Query 'PV query: What was the dosage prescribed to the subject for trazadone?' answered with 'Unknown. Subject did not report Trazodone during screening visit. Will follow up with subject. Thank you' (Site from Safety).	Cassandra Zehenny (b) (4)	16 Oct 2020 18:47:21
User opened query 'PV query: What was the dosage prescribed to the subject for trazadone?' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 19:57:39
DataPoint Verified.		12 Oct 2020 15:59:24
User closed query 'PV Query: Event term has been updated to Worsening depression, however, this condition was not reported on the medical history page. Please confirm if subject developed this condition prior to study enrollment and update medical history accordingly. Otherwise, please update event term to Depression.' (Site from Safety).		09 Oct 2020 13:24:49
User closed query 'PV Query: Please clarify if 5 Tablets of Trazodone constituted a drug overdose.' (Site from Safety).		09 Oct 2020 13:24:46
User closed query 'PV Query: Please clarify if the subject had been prescribed Trazodone as it is not currently listed as a concomitant medication. Please clarify trazodone tablet strength, daily dose and start date.' (Site from Safety).		09 Oct 2020 13:24:40
Query 'PV Query: Please clarify if 5 Tablets of Trazodone constituted a drug overdose.' answered with '5 tabs of trazodone is > the prescribed dosage.' (Site from Safety).	Joan Siegner (b) (4)	08 Oct 2020 16:44:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Event term has been updated to Worsening depression, however, this condition was not reported on the medical history page. Please confirm if subject developed this condition prior to study enrollment and update medical history accordingly. Otherwise, please update event term to Depression.' answered with 'data corrected' (Site from Safety).	Joan Siegner (b) (4)	08 Oct 2020 16:43:09
Query 'PV Query: Please clarify if the subject had been prescribed Trazodone as it is not currently listed as a concomitant medication. Please clarify trazodone tablet strength, daily dose and start date.' answered with 'had been prescribed in the past; dosage and dates unknown' (Site from Safety).	Joan Siegner (b) (4)	08 Oct 2020 16:42:37
User opened query 'PV Query: Event term has been updated to Worsening depression, however, this condition was not reported on the medical history page. Please confirm if subject developed this condition prior to study enrollment and update medical history accordingly. Otherwise, please update event term to Depression.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 21:29:05
User opened query 'PV Query: Please clarify if 5 Tablets of Trazodone constituted a drug overdose.' (Site from Safety).		07 Oct 2020 21:28:46
User opened query 'PV Query: Please clarify if the subject had been prescribed Trazodone as it is not currently listed as a concomitant medication. Please clarify trazodone tablet strength, daily dose and start date.' (Site from Safety).		07 Oct 2020 21:28:37
User closed query 'PV Query: It was reported the subject took five trazadone pills in attempt to sleep. Please provide indication for trazodone and consider adding condition to Med Hx' (Site from Safety).		01 Oct 2020 15:14:14
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		01 Oct 2020 15:14:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 15:14:08
Query 'PV Query: It was reported the subject took five trazadone pills in attempt to sleep. Please provide indication for trazodone and consider adding condition to Med Hx' answered with 'done' (Site from Safety).	Joan Siegner (b) (4)	30 Sep 2020 17:53:04
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'treatment provided in updated narrative' (Site from Safety).	Joan Siegner (b) (4)	30 Sep 2020 17:52:35
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'no relevant diagnostic tests for this condition' (Site from Safety).	Joan Siegner (b) (4)	30 Sep 2020 17:52:04
User entered 'SUBJECT TOOK 5 TRAZADONE IN ATTEMPT TO SLEEP AFTER HAVING DIFFICULTIES WITH HER DAUGHTER. WHEN HER DAUGHTER HAD TROUBLE AROUSING HER THE NEXT MORNING, SHE CALLED 911 AND SUBJECT WAS ADMITTED TO PSYCHIATRIC WARD OF LOCAL HOSPITAL. REMAINS HOSPITALIZED AT THIS TIME. 9/30/20 update: Inpatient records indicate that subject was treated with individual psychotherapy, group therapy and inpatient milieu, provided with med education and psychoeducation. Subject had a good response and the crisis which prompted the admission were "adequately resolved." reason for change: Data Entry Error	Joan Siegner (b) (4)	30 Sep 2020 17:51:14
User opened query 'PV Query: It was reported the subject took five trazadone pills in attempt to sleep. Please provide indication for trazodone and consider adding condition to Med Hx' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 14:43:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 14:43:01
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		29 Sep 2020 14:42:26
User entered 'Subject took 5 trazadone in attempt to sleep after having difficulties with her daughter. When her daughter had trouble arousing her the next morning, she called 911 and subject was admitted to psychiatric ward of local hospital. Remains hospitalized at this time. Will request medical records after discharge.'	Joan Siegner (b) (4)	21 Sep 2020 19:18:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Sep 2020 19:18:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Sep 2020 19:18:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Sep 2020 19:18:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:13:46

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:35:15
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:47:34
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:31:19

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: DROSPIRENONE;ETHINYLESTRADIOL, PRODUCTSYNONYM: GIANVI - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Sep 2020 19:33:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Sep 2020 19:33:40
Data point term sent to Coder	System	04 Sep 2020 19:32:39
User entered 'gianvi'	Stanley Dublin (b) (4)	04 Sep 2020 19:31:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:46

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:04:34
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
User closed query 'Per CDM: Prophylaxis = NO. However, vitamins. Supplements, contraceptives and vaccines are considered for prophylactic use. Please update response to Prophylaxis field as appropriate. Otherwise, clarify. ' (Site from DM). Query 'Per CDM: Prophylaxis = NO. However, vitamins. Supplements, contraceptives and vaccines are considered for prophylactic use. Please update response to Prophylaxis field as appropriate. Otherwise, clarify. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 12:40:20
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	09 Feb 2021 17:29:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Feb 2021 17:29:13
User opened query 'Per CDM: Prophylaxis = NO. However, vitamins. Supplements, contraceptives and vaccines are considered for prophylactic use. Please update response to Prophylaxis field as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 11:57:40
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	04 Sep 2020 19:31:49

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'birth control'	Stanley Doublin (b) (4)	04 Sep 2020 19:31:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'l'	Stanley Dublin (b) (4)	04 Sep 2020 19:31:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'tablet (TABLET)'	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:31:49

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered empty.	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:31:49

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'once daily (QD)'	Stanley Doublin (b) (4)	04 Sep 2020 19:31:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered empty.	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:31:49

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:31:49

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered empty.	Stanley Dublin (b) (4)	04 Sep 2020 19:31:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered '01 Jun 2019' reason for change: Data Entry Error	Stanley Dublin (b) (4)	04 Sep 2020 19:32:47
User entered 'un Jun 2019'	(b) (4)	
	Stanley Dublin (b) (4)	04 Sep 2020 19:31:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered '0'	Stanley Dublin (b) (4)	04 Sep 2020 19:31:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'Yes (Y)'	Stanley Dublin (b) (4)	04 Sep 2020 19:31:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered empty.	Stanley Dublin (b) (4)	04 Sep 2020 19:31:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'No (N)'	Stanley Dublin (b) (4)	04 Sep 2020 19:31:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	04 Sep 2020 19:31:49

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	04 Sep 2020 19:31:49

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 19:31:49

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:46

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	28 Sep 2020 12:54:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	28 Sep 2020 12:54:14
Data point term sent to Coder	System	08 Sep 2020 13:51:08
User closed query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	System	08 Sep 2020 13:51:04
Query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' answered with 'Updated per query request' (Site from System).	Heather Douds (b) (4)	08 Sep 2020 13:51:04
User entered 'C gummie vitamin [vitamin c]' reason for change: Per Query Resolution	Heather Douds (b) (4)	08 Sep 2020 13:50:55
User opened query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	07 Sep 2020 12:44:42
Data point term sent to Coder	System	04 Sep 2020 19:32:41
User entered 'c gummie vitamin'	Stanley Dublin (b) (4)	04 Sep 2020 19:32:36

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 01:07:27
DataPoint Un-verified.	Stanley Doublin (b) (4)	11 Nov 2020 16:57:10
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	11 Nov 2020 16:57:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'No (N)'	Stanley Doublin (b) (4)	04 Sep 2020 19:32:36
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'health promotion'	Stanley Doublin (b) (4)	04 Sep 2020 19:32:36
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered '250'	Stanley Dublin (b) (4)	04 Sep 2020 19:32:36
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'mg (mg)'	Stanley Doublin (b) (4)	04 Sep 2020 19:32:36
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered empty.	Stanley Dublin (b) (4)	04 Sep 2020 19:32:36
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'once daily (QD)'	Stanley Doublin (b) (4)	04 Sep 2020 19:32:36
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered empty.	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:32:36

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4)	04 Sep 2020 19:32:36
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered empty.	Stanley Dublin (b) (4)	04 Sep 2020 19:32:36
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered '01 Jun 2018'	Stanley Dublin (b) (4)	04 Sep 2020 19:32:36
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered '0'	Stanley Dublin (b) (4)	04 Sep 2020 19:32:36
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'Yes (Y)'	Stanley Dublin (b) (4)	04 Sep 2020 19:32:36
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered empty.	Stanley Dublin (b) (4)	04 Sep 2020 19:32:36
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'No (N)'	Stanley Dublin (b) (4)	04 Sep 2020 19:32:36
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	04 Sep 2020 19:32:36

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Sep 2020 19:32:36

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 19:32:36

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Sep 2020 07:00:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Sep 2020 07:00:53
Data point term sent to Coder	System	04 Sep 2020 19:34:45
User entered 'multivitmain'	Stanley Dublin (b) (4)	04 Sep 2020 19:33:59
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 01:07:32
DataPoint Un-verified.	Stanley Doublin (b) (4)	11 Nov 2020 16:57:15
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	11 Nov 2020 16:57:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'No (N)'	Stanley Doublin (b) (4)	04 Sep 2020 19:33:59
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'health promotion'	Stanley Dublin (b) (4)	04 Sep 2020 19:33:59
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'l'	Stanley Dublin (b) (4)	04 Sep 2020 19:33:59
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'tablet (TABLET)'	Stanley Doublin (b) (4)	04 Sep 2020 19:33:59
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered empty.	Stanley Dublin (b) (4)	04 Sep 2020 19:33:59
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'once daily (QD)'	Stanley Doublin (b) (4)	04 Sep 2020 19:33:59
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered empty.	Stanley Dublin (b) (4)	04 Sep 2020 19:33:59
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4)	04 Sep 2020 19:33:59
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered empty.	Stanley Dublin (b) (4)	04 Sep 2020 19:33:59
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered '01 Jun 2018'	Stanley Dublin (b) (4)	04 Sep 2020 19:33:59
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered '0'	Stanley Dublin (b) (4)	04 Sep 2020 19:33:59
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'Yes (Y)'	Stanley Dublin (b) (4)	04 Sep 2020 19:33:59
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered empty.	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:33:59

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'No (N)'	Stanley Dublin (b) (4)	04 Sep 2020 19:33:59
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 19:33:59

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Sep 2020 19:33:59

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 19:33:59

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Sep 2020 07:09:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Sep 2020 07:09:56
Data point term sent to Coder	System	04 Sep 2020 19:35:48
User entered 'potassium'	Stanley Doublin (b) (4)	04 Sep 2020 19:34:49
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 01:07:37
DataPoint Un-verified.	Stanley Doublin (b) (4)	11 Nov 2020 16:57:20
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	11 Nov 2020 16:57:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'No (N)'	Stanley Doublin (b) (4)	04 Sep 2020 19:34:49
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'health promotion'	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:34:49

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered '99'	Stanley Dublin (b) (4)	04 Sep 2020 19:34:49
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'mg (mg)'	Stanley Doublin (b) (4)	04 Sep 2020 19:34:49
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered empty.	Stanley Dublin (b) (4)	04 Sep 2020 19:34:49
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'once daily (QD)'	Stanley Doublin (b) (4)	04 Sep 2020 19:34:49
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered empty.	Stanley Dublin (b) (4)	04 Sep 2020 19:34:49
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:34:49

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered empty.	Stanley Dublin (b) (4)	04 Sep 2020 19:34:49
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered '01 Jun 2018'	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:34:49

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered '0'	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:34:49

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	04 Sep 2020 19:34:49
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered empty.	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:34:49

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:34:49

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	04 Sep 2020 19:34:49

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Sep 2020 19:34:49

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 19:34:49

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
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)	04 Sep 2020 19:36:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 19:36:46
Data point term sent to Coder	System	04 Sep 2020 19:35:49
User entered 'magnesium'	Stanley Doublin (b) (4)	04 Sep 2020 19:35:21
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 01:07:41
DataPoint Un-verified.	Stanley Doublin (b) (4)	11 Nov 2020 16:57:26
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	11 Nov 2020 16:57:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'No (N)'	Stanley Doublin (b) (4)	04 Sep 2020 19:35:21
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'health promotion'	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:35:21

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered '250'	Stanley Dublin (b) (4)	04 Sep 2020 19:35:21
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'mg (mg)'	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:35:21

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered empty.	Stanley Dublin (b) (4)	04 Sep 2020 19:35:21
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'once daily (QD)'	Stanley Doublin (b) (4)	04 Sep 2020 19:35:21
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered empty.	Stanley Dublin (b) (4)	04 Sep 2020 19:35:21
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4)	04 Sep 2020 19:35:21
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered empty.	Stanley Dublin (b) (4)	04 Sep 2020 19:35:21
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered '01 Jun 2018'	Stanley Dublin (b) (4)	04 Sep 2020 19:35:21
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered '0'	Stanley Dublin (b) (4)	04 Sep 2020 19:35:21
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	04 Sep 2020 19:35:21
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered empty.	Stanley Dublin (b) (4) (b) (4)	04 Sep 2020 19:35:21

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'No (N)'	Stanley Dublin (b) (4)	04 Sep 2020 19:35:21
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	04 Sep 2020 19:35:21

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Sep 2020 19:35:21

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 19:35:21

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:46

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VENLAFAXINE HYDROCHLORIDE, PRODUCTSYNONYM: EFFEXOR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Feb 2021 10:42:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 10:42:43
Data point term sent to Coder Coding entries removed.	System Cassandra Zehenny (b) (4)	03 Feb 2021 22:25:14 03 Feb 2021 22:25:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VENLAFAXINE HYDROCHLORIDE, PRODUCTSYNONYM: EFFEXOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 16:09:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 16:09:27
Data point term sent to Coder Coding entries removed.	System Cassandra Zehenny (b) (4)	03 Nov 2020 16:08:52 03 Nov 2020 16:08:11
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: VENLAFAXINE HYDROCHLORIDE, PRODUCTSYNONYM: EFFEXOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 18:53:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 18:53:00
Data point term sent to Coder User entered 'effexor'	System Mikayla Frye (b) (4)	25 Sep 2020 18:51:57 25 Sep 2020 18:51:17

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	25 Sep 2020 18:51:17

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 16:35:33
User closed query 'Please update to worsening depression ' (Site from CRA).		04 Feb 2021 16:35:31
Query 'Please update to worsening depression ' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4)	03 Feb 2021 22:25:09
DataPoint Un-verified.	(b) (4)	
	Cassandra Zehenny (b) (4)	03 Feb 2021 22:25:05
	(b) (4)	
User entered 'worsening DEPRESSION' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	03 Feb 2021 22:25:05
	(b) (4)	
User opened query 'Please update to worsening depression ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 20:53:49
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).		05 Nov 2020 05:43:57
DataPoint Verified.		
		04 Nov 2020 16:03:25
DataPoint Un-verified.		04 Nov 2020 16:01:44
DataPoint Verified.		04 Nov 2020 16:01:36
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.	Cassandra Zehenny (b) (4)	03 Nov 2020 16:08:24
	(b) (4)	
' answered with 'data error, prescribed for depression' (Site from DM).		
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	03 Nov 2020 16:08:11
	(b) (4)	
User entered 'depression' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	03 Nov 2020 16:08:11
	(b) (4)	
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 09:44:33

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:46

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'anxiety'	Mikayla Frye (b) (4) (b) (4)	25 Sep 2020 18:51:17

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered '75' reason for change: Data Entry Error	Joan Siegner (b) (4)	25 Sep 2020 19:31:47
User entered '1'	Mikayla Frye (b) (4)	25 Sep 2020 18:51:17
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'mg (mg)' reason for change: Data Entry Error	Joan Siegner (b) (4)	25 Sep 2020 19:31:47
User entered 'capsule (CAPSULE)'	Mikayla Frye (b) (4)	25 Sep 2020 18:51:17
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered empty.	Mikayla Frye (b) (4)	25 Sep 2020 18:51:17
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'once daily (QD)'	Mikayla Frye (b) (4) (b) (4)	25 Sep 2020 18:51:17

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered empty.	Mikayla Frye (b) (4)	25 Sep 2020 18:51:17
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4) (b) (4)	25 Sep 2020 18:51:17

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered empty.	Mikayla Frye (b) (4)	25 Sep 2020 18:51:17
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:46

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

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered '24 Sep 2020'	Mikayla Frye (b) (4)	25 Sep 2020 18:51:17
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered '0'	Mikayla Frye (b) (4)	25 Sep 2020 18:51:17
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:46

[Ongoing?](#)

Audit	User	Time (GMT)
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).	(b) (4), (b) (6)	25 Feb 2021 06:20:28
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 'exacerbation of condition resolved, meds continue for medical condition' (Site from DM).	Heather Douds (b) (4) (b) (4)	22 Feb 2021 21:18:30
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).	(b) (4), (b) (6)	22 Feb 2021 16:36:50
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	25 Sep 2020 18:51:17

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered empty.	Mikayla Frye (b) (4) (b) (4)	25 Sep 2020 18:51:17

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	25 Sep 2020 18:51:17

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	25 Sep 2020 18:51:17

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Sep 2020 18:51:17

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 18:51:17

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:13
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: ESCITALOPRAM OXALATE, PRODUCTSYNONYM: LEXAPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 10:58:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 10:58:52
Data point term sent to Coder	System	03 Feb 2021 22:25:14
Coding entries removed.	Cassandra Zehenny (b) (4) (b) (4)	03 Feb 2021 22:24:48
User closed query 'Per PCP notes, subject was on Valium at the time of admission, Please try to retrieve information from subject about this med at the next safety call and update conmeds as needed. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 01:17:32
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:13:25
Query 'Per PCP notes, subject was on Valium at the time of admission, Please try to retrieve information from subject about this med at the next safety call and update conmeds as needed. Thank you! ' answered with 'Data pending' (Site from CRA).	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 15:21:42
User opened query 'Per PCP notes, subject was on Valium at the time of admission, Please try to retrieve information from subject about this med at the next safety call and update conmeds as needed. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	12 Oct 2020 16:05:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: ESCITALOPRAM OXALATE, PRODUCTSYNONYM: LEXAPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 17:26:44

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:46

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	28 Sep 2020 17:26:44
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	28 Sep 2020 17:25:23
User entered 'lexapro'	Joan Siegner (b) (4)	28 Sep 2020 17:25:05

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:13
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
User closed query 'Please consider capturing Trazodine that subject took on monday night 14Sep , 5 tabs X 10 mg PO. ' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 15:55:00
Query 'Please consider capturing Trazodine that subject took on monday night 14Sep , 5 tabs X 10 mg PO. ' answered with 'updated, exact dosage unknown' (Site from CRA).	Cassandra Zehenny (b) (4) (b) (4)	16 Nov 2020 15:21:07
User opened query 'Please consider capturing Trazodine that subject took on monday night 14Sep , 5 tabs X 10 mg PO. ' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'No (N)'	Joan Siegner (b) (4)	28 Sep 2020 17:25:05

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	04 Feb 2021 16:35:42
User closed query 'Please update to worsening depression to match SAE term. ' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 16:35:41
Query 'Please update to worsening depression to match SAE term. ' answered with 'updated, thank you' (Site from CRA).	Cassandra Zehenny (b) (4)	03 Feb 2021 22:24:55
DataPoint Un-verified.	(b) (4)	
	Cassandra Zehenny (b) (4)	03 Feb 2021 22:24:48
User entered 'worsening DEPRESSION' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	03 Feb 2021 22:24:48
User opened query 'Please update to worsening depression to match SAE term. ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 20:54:11
DataPoint Verified.		29 Oct 2020 20:16:08
User entered 'depression'	Joan Siegner (b) (4)	28 Sep 2020 17:25:05

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:13
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered '10'	Joan Siegner (b) (4)	28 Sep 2020 17:25:05

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	29 Oct 2020 20:16:08
User entered 'mg (mg)'	Joan Siegner (b) (4)	28 Sep 2020 17:25:05

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	29 Oct 2020 20:16:08
User entered empty.	Joan Siegner (b) (4)	28 Sep 2020 17:25:05

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	29 Oct 2020 20:16:08
User entered 'once daily (QD)'	Joan Siegner (b) (4)	28 Sep 2020 17:25:05

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:13
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered empty.	Joan Siegner (b) (4)	28 Sep 2020 17:25:05

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:13
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'Oral (ORAL)'	Joan Siegner (b) (4)	28 Sep 2020 17:25:05

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	29 Oct 2020 20:16:08
User entered empty.	Joan Siegner (b) (4)	28 Sep 2020 17:25:05

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	29 Oct 2020 20:16:08
User entered '16 Sep 2020'	Joan Siegner (b) (4)	28 Sep 2020 17:25:05

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:13
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered '0'	Joan Siegner (b) (4)	28 Sep 2020 17:25:05

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:13
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'No (N)'	Joan Siegner (b) (4)	28 Sep 2020 17:25:05

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	04 Nov 2020 16:02:28
User closed query 'Per source the stop date is 21Sep. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 16:02:26
Query 'Per source the stop date is 21Sep. Please reconcile. ' answered with 'data corrected' (Site from CRA).	Joan Siegner (b) (4)	30 Oct 2020 15:37:50
DataPoint Un-verified.	Joan Siegner (b) (4)	30 Oct 2020 15:37:43
User entered '21 Sep 2020' reason for change: Data Entry Error	Joan Siegner (b) (4)	30 Oct 2020 15:37:43
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User opened query 'Per source the stop date is 21Sep. Please reconcile. ' (Site from CRA).	(b) (4)	29 Oct 2020 20:15:03
User entered '24 Sep 2020'	Joan Siegner (b) (4)	28 Sep 2020 17:25:05

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:13
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:16:08
User entered 'No (N)'	Joan Siegner (b) (4)	28 Sep 2020 17:25:05

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:13
User entered 'I'	System	28 Sep 2020 17:25:05

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:13
User entered 'I'	System	28 Sep 2020 17:25:05

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:13
User entered '804 (804)'	System	28 Sep 2020 17:25:05

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 07:46:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 07:46:59
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 15:56:02
Data point term sent to Coder	System	16 Nov 2020 15:24:08
User entered 'Trazodone'	Cassandra Zehenny (b) (4) (b) (4)	16 Nov 2020 15:23:44

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 15:56:13
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	16 Nov 2020 15:23:44

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 15:56:40
User entered 'Worsening depression'	Cassandra Zehenny (b) (4)	16 Nov 2020 15:23:44
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	16 Nov 2020 22:48:09
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 22:48:09
	Cassandra Zehenny (b) (4)	16 Nov 2020 22:38:54
User entered '50' reason for change: Data Entry Error	(b) (4)	16 Nov 2020 22:38:54
DataPoint Verified.	Cassandra Zehenny (b) (4)	16 Nov 2020 22:38:54
	(b) (4)	16 Nov 2020 15:57:53
User entered '5'	(b) (4), (b) (6)	16 Nov 2020 15:57:53
	Cassandra Zehenny (b) (4)	16 Nov 2020 15:23:44
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	16 Nov 2020 22:48:07
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 22:48:07
	Cassandra Zehenny (b) (4)	16 Nov 2020 22:38:54
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4)	16 Nov 2020 22:38:54
DataPoint Verified.	Cassandra Zehenny (b) (4)	16 Nov 2020 22:38:54
	(b) (4)	16 Nov 2020 15:58:23
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	16 Nov 2020 15:58:23
	Cassandra Zehenny (b) (4)	16 Nov 2020 15:23:44
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 15:58:55
User entered empty.	Cassandra Zehenny (b) (4)	16 Nov 2020 15:23:44
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 15:59:33
User entered 'once (ONCE)'	Cassandra Zehenny (b) (4) (b) (4)	16 Nov 2020 15:23:44

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:00:13
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	16 Nov 2020 15:23:44

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:00:42
User entered 'Oral (ORAL)'	Cassandra Zehenny (b) (4) (b) (4)	16 Nov 2020 15:23:44

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:01:38
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	16 Nov 2020 15:23:44

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM). Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6) Cassandra Zehenny (b) (4) (b) (4)	02 Feb 2021 05:04:42 28 Jan 2021 20:19:06
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 03:27:08
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:02:02
User entered '14 Sep 2020'	Cassandra Zehenny (b) (4) (b) (4)	16 Nov 2020 15:23:44

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:02:14
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	16 Nov 2020 15:23:44

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 16:03:02
User entered 'No (N)'	Cassandra Zehenny (b) (4)	16 Nov 2020 15:23:44
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	16 Nov 2020 16:03:46
User entered '14 Sep 2020'	Cassandra Zehenny (b) (4)	16 Nov 2020 15:23:44
	(b) (4)	

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:17
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:04:11
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	16 Nov 2020 15:23:44

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:17
User entered empty.	System	16 Nov 2020 15:23:44

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:17
User entered empty.	System	16 Nov 2020 15:23:44

US3552331

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:08:17
User entered empty.	System	16 Nov 2020 15:23:44

US3552331

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:13:46

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 20:31:31
User entered 'No (N)'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:25:43
	(b) (4)	

US3552331

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:13:46

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 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:30:21
User entered '01 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Nov 2020 15:27:25
User entered '1 Oct 2020'	Heather Douds (b) (4) (b) (4)	01 Oct 2020 18:53:27

US3552331

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:13:46

[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 18:49:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:30:21
User closed query 'Per CRF guide, if the season for dosing dist was SAE, there should be an option to enter "SAE" instead of "AE". Please update the entry if option "SAE" is available. ' (Site from CRA).		13 Oct 2020 16:48:48
Query 'Per CRF guide, if the season for dosing dist was SAE, there should be an option to enter "SAE" instead of "AE". Please update the entry if option "SAE" is available. ' answered with 'updated' (Site from CRA).	Heather Douds (b) (4) (b) (4)	12 Oct 2020 19:31:29
User entered 'SAE (specify) (SAE)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	12 Oct 2020 19:31:24
User opened query 'Per CRF guide, if the season for dosing dist was SAE, there should be an option to enter "SAE" instead of "AE". Please update the entry if option "SAE" is available. ' (Site from CRA).	(b) (4), (b) (6)	12 Oct 2020 16:17:26
User entered 'AE (specify) (ADVERSE EVENT)'	Heather Douds (b) (4) (b) (4)	01 Oct 2020 18:53:27

US3552331

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:13:46

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 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Nov 2020 16:03:39
User closed query 'Per CDM: Please record SAE record number instead of details .' (Site from DM).		20 Nov 2020 09:53:03
Query 'Per CDM: Please record SAE record number instead of details .' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	19 Nov 2020 15:27:31
DataPoint Un-verified.	(b) (4)	
	Cassandra Zehenny (b) (4)	19 Nov 2020 15:27:17
User entered 'SAE #1' reason for change: Per Query Resolution	(b) (4)	
	Cassandra Zehenny (b) (4)	19 Nov 2020 15:27:17
User opened query 'Per CDM: Please record SAE record number instead of details .' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 11:48:17
DataPoint Verified.		10 Nov 2020 20:30:21
User entered '#1 - episode of worsening depression'	Heather Douds (b) (4)	01 Oct 2020 18:53:27
	(b) (4)	

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:07:55
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'USA-US089-2020-MRNA-1273-P301000004'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:07:56
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'Yes (Y)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:07:58
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:00
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:01
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'Yes (Y)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:03
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:05
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'sharon'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'frey'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:50:18
Un-reviewed for Safety.	System	29 Jan 2021 18:39:11
DataPoint Un-verified.	System	29 Jan 2021 18:39:11
User entered empty.	System	29 Jan 2021 18:39:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 18:38:57
DataPoint Verified.		10 Nov 2020 20:30:50
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Nov 2020 15:26:54
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	10 Nov 2020 14:50:40
User entered empty.	System	10 Nov 2020 14:50:40
Reviewed for Safety.	System	10 Nov 2020 14:50:40
	(b) (4), (b) (6)	10 Nov 2020 14:50:29
DataPoint Verified.		09 Nov 2020 17:33:08
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:05
	(b) (4)	

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:50:20
Un-reviewed for Safety.	System	29 Jan 2021 18:39:11
DataPoint Un-verified.	System	29 Jan 2021 18:39:11
User entered empty.	System	29 Jan 2021 18:39:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 18:38:57
DataPoint Verified.		10 Nov 2020 20:30:52
User entered 'St. Louis' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Nov 2020 15:26:54
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 14:50:40
DataPoint Un-verified.	System	10 Nov 2020 14:50:40
User entered empty.	System	10 Nov 2020 14:50:40
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:50:29
DataPoint Verified.		09 Nov 2020 17:33:10
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:05
	(b) (4)	

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:14
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'MO'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:50:21
Un-reviewed for Safety.	System	29 Jan 2021 18:39:11
DataPoint Un-verified.	System	29 Jan 2021 18:39:11
User entered empty.	System	29 Jan 2021 18:39:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 18:38:57
DataPoint Verified.		10 Nov 2020 20:30:54
User entered '63104' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Nov 2020 15:26:54
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 14:50:40
DataPoint Un-verified.	System	10 Nov 2020 14:50:40
User entered empty.	System	10 Nov 2020 14:50:40
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:50:29
DataPoint Verified.		09 Nov 2020 17:33:11
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:05
	(b) (4)	

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 16:08:15
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:06:53
User entered 'US'	System	22 Sep 2020 14:03:47

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
User entered '9'	(b) (4)	29 Jan 2021 18:39:11
User entered '8'	System	10 Nov 2020 14:50:40
User entered '7'	System	27 Oct 2020 12:24:34
User entered '6'	System	19 Oct 2020 19:46:30
User entered '5'	System	13 Oct 2020 14:20:46
User entered '4'	System	09 Oct 2020 13:26:20
User entered '3'	System	02 Oct 2020 12:14:25
User entered '2'	System	29 Sep 2020 13:07:01
User entered '1'	System	22 Sep 2020 14:03:47

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:07:55
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'USA-US089-2020-MRNA-1273-P301000004'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:07:56
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'Yes (Y)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:07:58
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:00
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:01
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'Yes (Y)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:03
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:05
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'sharon'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'frey'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:50:18
Un-reviewed for Safety.	System	29 Jan 2021 18:39:11
DataPoint Un-verified.	System	29 Jan 2021 18:39:11
User entered empty.	System	29 Jan 2021 18:39:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 18:38:57
DataPoint Verified.		10 Nov 2020 20:30:50
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Nov 2020 15:26:54
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	10 Nov 2020 14:50:40
User entered empty.	System	10 Nov 2020 14:50:40
Reviewed for Safety.	System	10 Nov 2020 14:50:40
	(b) (4), (b) (6)	10 Nov 2020 14:50:29
DataPoint Verified.		09 Nov 2020 17:33:08
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:05
	(b) (4)	

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:50:20
Un-reviewed for Safety.	System	29 Jan 2021 18:39:11
DataPoint Un-verified.	System	29 Jan 2021 18:39:11
User entered empty.	System	29 Jan 2021 18:39:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 18:38:57
DataPoint Verified.		10 Nov 2020 20:30:52
User entered 'St. Louis' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Nov 2020 15:26:54
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 14:50:40
DataPoint Un-verified.	System	10 Nov 2020 14:50:40
User entered empty.	System	10 Nov 2020 14:50:40
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:50:29
DataPoint Verified.		09 Nov 2020 17:33:10
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:05
	(b) (4)	

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:14
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'MO'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:50:21
Un-reviewed for Safety.	System	29 Jan 2021 18:39:11
DataPoint Un-verified.	System	29 Jan 2021 18:39:11
User entered empty.	System	29 Jan 2021 18:39:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 18:38:57
DataPoint Verified.		10 Nov 2020 20:30:54
User entered '63104' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Nov 2020 15:26:54
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 14:50:40
DataPoint Un-verified.	System	10 Nov 2020 14:50:40
User entered empty.	System	10 Nov 2020 14:50:40
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:50:29
DataPoint Verified.		09 Nov 2020 17:33:11
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:05
	(b) (4)	

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:15
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:06:53
User entered 'US'	System	22 Sep 2020 14:03:47

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
User entered '9'	(b) (4)	29 Jan 2021 18:39:11
User entered '8'	System	10 Nov 2020 14:50:40
User entered '7'	System	27 Oct 2020 12:24:34
User entered '6'	System	19 Oct 2020 19:46:30
User entered '5'	System	13 Oct 2020 14:20:46
User entered '4'	System	09 Oct 2020 13:26:20
User entered '3'	System	02 Oct 2020 12:14:25
User entered '2'	System	29 Sep 2020 13:07:01
User entered '1'	System	22 Sep 2020 14:03:47

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:13:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:46:38
User entered '22/Sep/2020 10:03'	System	22 Sep 2020 14:03:47

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:13:46

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.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	05 Nov 2020 21:46:40
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:06:53
User entered 'l'		22 Sep 2020 14:03:47

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:07:55
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'USA-US089-2020-MRNA-1273-P301000004'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:07:56
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'Yes (Y)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:07:58
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:08:00
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:01
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'Yes (Y)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:03
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:05
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'sharon'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'frey'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:50:18
Un-reviewed for Safety.	System	29 Jan 2021 18:39:11
DataPoint Un-verified.	System	29 Jan 2021 18:39:11
User entered empty.	System	29 Jan 2021 18:39:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 18:38:57
DataPoint Verified.		10 Nov 2020 20:30:50
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Nov 2020 15:26:54
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 14:50:40
DataPoint Un-verified.	System	10 Nov 2020 14:50:40
User entered empty.	System	10 Nov 2020 14:50:40
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:50:29
DataPoint Verified.		09 Nov 2020 17:33:08
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:05
	(b) (4)	

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:50:20
Un-reviewed for Safety.	System	29 Jan 2021 18:39:11
DataPoint Un-verified.	System	29 Jan 2021 18:39:11
User entered empty.	System	29 Jan 2021 18:39:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 18:38:57
DataPoint Verified.		10 Nov 2020 20:30:52
User entered 'St. Louis' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Nov 2020 15:26:54
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 14:50:40
DataPoint Un-verified.	System	10 Nov 2020 14:50:40
User entered empty.	System	10 Nov 2020 14:50:40
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:50:29
DataPoint Verified.		09 Nov 2020 17:33:10
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:05
	(b) (4)	

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:14
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'MO'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:50:21
Un-reviewed for Safety.	System	29 Jan 2021 18:39:11
DataPoint Un-verified.	System	29 Jan 2021 18:39:11
User entered empty.	System	29 Jan 2021 18:39:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 18:38:57
DataPoint Verified.		10 Nov 2020 20:30:54
User entered '63104' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Nov 2020 15:26:54
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 14:50:40
DataPoint Un-verified.	System	10 Nov 2020 14:50:40
User entered empty.	System	10 Nov 2020 14:50:40
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:50:29
DataPoint Verified.		09 Nov 2020 17:33:11
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:05
	(b) (4)	

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:15
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:06:53
User entered 'US'	System	22 Sep 2020 14:03:47

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
User entered '9'	(b) (4)	29 Jan 2021 18:39:11
User entered '8'	System	10 Nov 2020 14:50:40
User entered '7'	System	27 Oct 2020 12:24:34
User entered '6'	System	19 Oct 2020 19:46:30
User entered '5'	System	13 Oct 2020 14:20:46
User entered '4'	System	09 Oct 2020 13:26:20
User entered '3'	System	02 Oct 2020 12:14:25
User entered '2'	System	29 Sep 2020 13:07:01
User entered '1'	System	22 Sep 2020 14:03:47

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:13:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:46:44
User entered '29/Sep/2020 09:07'	System	29 Sep 2020 13:07:01

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:13:46

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.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	05 Nov 2020 21:46:45
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:14:15
User entered 'l'		29 Sep 2020 13:07:01

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:07:55
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'USA-US089-2020-MRNA-1273-P301000004'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:07:56
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'Yes (Y)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:07:58
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:00
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:01
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'Yes (Y)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:03
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:05
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'sharon'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'frey'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:50:18
Un-reviewed for Safety.	System	29 Jan 2021 18:39:11
DataPoint Un-verified.	System	29 Jan 2021 18:39:11
User entered empty.	System	29 Jan 2021 18:39:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 18:38:57
DataPoint Verified.		10 Nov 2020 20:30:50
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Nov 2020 15:26:54
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	10 Nov 2020 14:50:40
User entered empty.	System	10 Nov 2020 14:50:40
Reviewed for Safety.	System	10 Nov 2020 14:50:40
	(b) (4), (b) (6)	10 Nov 2020 14:50:29
DataPoint Verified.		09 Nov 2020 17:33:08
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:05
	(b) (4)	

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:50:20
Un-reviewed for Safety.	System	29 Jan 2021 18:39:11
DataPoint Un-verified.	System	29 Jan 2021 18:39:11
User entered empty.	System	29 Jan 2021 18:39:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 18:38:57
DataPoint Verified.		10 Nov 2020 20:30:52
User entered 'St. Louis' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Nov 2020 15:26:54
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 14:50:40
DataPoint Un-verified.	System	10 Nov 2020 14:50:40
User entered empty.	System	10 Nov 2020 14:50:40
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:50:29
DataPoint Verified.		09 Nov 2020 17:33:10
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:05
	(b) (4)	

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:14
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'MO'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:50:21
Un-reviewed for Safety.	System	29 Jan 2021 18:39:11
DataPoint Un-verified.	System	29 Jan 2021 18:39:11
User entered empty.	System	29 Jan 2021 18:39:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 18:38:57
DataPoint Verified.		10 Nov 2020 20:30:54
User entered '63104' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Nov 2020 15:26:54
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 14:50:40
DataPoint Un-verified.	System	10 Nov 2020 14:50:40
User entered empty.	System	10 Nov 2020 14:50:40
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:50:29
DataPoint Verified.		09 Nov 2020 17:33:11
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:05
	(b) (4)	

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:15
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:06:53
User entered 'US'	System	22 Sep 2020 14:03:47

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
User entered '9'	(b) (4)	29 Jan 2021 18:39:11
User entered '8'	System	10 Nov 2020 14:50:40
User entered '7'	System	27 Oct 2020 12:24:34
User entered '6'	System	19 Oct 2020 19:46:30
User entered '5'	System	13 Oct 2020 14:20:46
User entered '4'	System	09 Oct 2020 13:26:20
User entered '3'	System	02 Oct 2020 12:14:25
User entered '2'	System	29 Sep 2020 13:07:01
User entered '1'	System	22 Sep 2020 14:03:47

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:13:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:46:49
User entered '02/Oct/2020 08:14'	System	02 Oct 2020 12:14:25

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:13:46

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.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	05 Nov 2020 21:46:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 13:25:59
User entered 'l'		02 Oct 2020 12:14:25

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:07:55
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'USA-US089-2020-MRNA-1273-P301000004'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:07:56
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'Yes (Y)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:07:58
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:00
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:01
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'Yes (Y)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:03
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:05
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'sharon'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'frey'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:50:18
Un-reviewed for Safety.	System	29 Jan 2021 18:39:11
DataPoint Un-verified.	System	29 Jan 2021 18:39:11
User entered empty.	System	29 Jan 2021 18:39:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 18:38:57
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:30:50
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Nov 2020 15:26:54
Un-reviewed for Safety.	System	10 Nov 2020 14:50:40
DataPoint Un-verified.	System	10 Nov 2020 14:50:40
User entered empty.	System	10 Nov 2020 14:50:40
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:50:29
DataPoint Verified.		09 Nov 2020 17:33:08
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:05
	(b) (4)	

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:50:20
Un-reviewed for Safety.	System	29 Jan 2021 18:39:11
DataPoint Un-verified.	System	29 Jan 2021 18:39:11
User entered empty.	System	29 Jan 2021 18:39:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 18:38:57
DataPoint Verified.		10 Nov 2020 20:30:52
User entered 'St. Louis' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Nov 2020 15:26:54
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 14:50:40
DataPoint Un-verified.	System	10 Nov 2020 14:50:40
User entered empty.	System	10 Nov 2020 14:50:40
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:50:29
DataPoint Verified.		09 Nov 2020 17:33:10
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:05
	(b) (4)	

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:14
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'MO'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:50:21
Un-reviewed for Safety.	System	29 Jan 2021 18:39:11
DataPoint Un-verified.	System	29 Jan 2021 18:39:11
User entered empty.	System	29 Jan 2021 18:39:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 18:38:57
DataPoint Verified.		10 Nov 2020 20:30:54
User entered '63104' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Nov 2020 15:26:54
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 14:50:40
DataPoint Un-verified.	System	10 Nov 2020 14:50:40
User entered empty.	System	10 Nov 2020 14:50:40
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:50:29
DataPoint Verified.		09 Nov 2020 17:33:11
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:05
	(b) (4)	

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:15
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:06:53
User entered 'US'	System	22 Sep 2020 14:03:47

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
User entered '9'	(b) (4)	29 Jan 2021 18:39:11
User entered '8'	System	10 Nov 2020 14:50:40
User entered '7'	System	27 Oct 2020 12:24:34
User entered '6'	System	19 Oct 2020 19:46:30
User entered '5'	System	13 Oct 2020 14:20:46
User entered '4'	System	09 Oct 2020 13:26:20
User entered '3'	System	02 Oct 2020 12:14:25
User entered '2'	System	29 Sep 2020 13:07:01
User entered '1'	System	22 Sep 2020 14:03:47

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:13:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:46:54
User entered '09/Oct/2020 13:26'	System	09 Oct 2020 13:26:20

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:13:46

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.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	05 Nov 2020 21:46:55
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:20:33
User entered 'l'		09 Oct 2020 13:26:20

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:07:55
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'USA-US089-2020-MRNA-1273-P301000004'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:07:56
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'Yes (Y)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:07:58
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:00
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:01
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'Yes (Y)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:03
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:05
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'sharon'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'frey'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:50:18
Un-reviewed for Safety.	System	29 Jan 2021 18:39:11
DataPoint Un-verified.	System	29 Jan 2021 18:39:11
User entered empty.	System	29 Jan 2021 18:39:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 18:38:57
DataPoint Verified.		10 Nov 2020 20:30:50
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Nov 2020 15:26:54
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	10 Nov 2020 14:50:40
User entered empty.	System	10 Nov 2020 14:50:40
Reviewed for Safety.	System	10 Nov 2020 14:50:40
	(b) (4), (b) (6)	10 Nov 2020 14:50:29
DataPoint Verified.		09 Nov 2020 17:33:08
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:05
	(b) (4)	

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:50:20
Un-reviewed for Safety.	System	29 Jan 2021 18:39:11
DataPoint Un-verified.	System	29 Jan 2021 18:39:11
User entered empty.	System	29 Jan 2021 18:39:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 18:38:57
DataPoint Verified.		10 Nov 2020 20:30:52
User entered 'St. Louis' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Nov 2020 15:26:54
Un-reviewed for Safety.	System	10 Nov 2020 14:50:40
DataPoint Un-verified.	System	10 Nov 2020 14:50:40
User entered empty.	System	10 Nov 2020 14:50:40
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:50:29
DataPoint Verified.		09 Nov 2020 17:33:10
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:05
	(b) (4)	

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:14
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'MO'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:50:21
Un-reviewed for Safety.	System	29 Jan 2021 18:39:11
DataPoint Un-verified.	System	29 Jan 2021 18:39:11
User entered empty.	System	29 Jan 2021 18:39:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 18:38:57
DataPoint Verified.		10 Nov 2020 20:30:54
User entered '63104' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Nov 2020 15:26:54
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 14:50:40
DataPoint Un-verified.	System	10 Nov 2020 14:50:40
User entered empty.	System	10 Nov 2020 14:50:40
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:50:29
DataPoint Verified.		09 Nov 2020 17:33:11
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:05
	(b) (4)	

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:15
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:06:53
User entered 'US'	System	22 Sep 2020 14:03:47

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
User entered '9'	(b) (4)	29 Jan 2021 18:39:11
User entered '8'	System	10 Nov 2020 14:50:40
User entered '7'	System	27 Oct 2020 12:24:34
User entered '6'	System	19 Oct 2020 19:46:30
User entered '5'	System	13 Oct 2020 14:20:46
User entered '4'	System	09 Oct 2020 13:26:20
User entered '3'	System	02 Oct 2020 12:14:25
User entered '2'	System	29 Sep 2020 13:07:01
User entered '1'	System	22 Sep 2020 14:03:47

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:13:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:47:00
User entered '13/Oct/2020 14:20'	System	13 Oct 2020 14:20:46

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:13:46

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.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	05 Nov 2020 21:47:02
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 19:46:22
User entered 'l'		13 Oct 2020 14:20:46

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:07:55
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'USA-US089-2020-MRNA-1273-P301000004'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:07:56
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'Yes (Y)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:07:58
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:00
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:01
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'Yes (Y)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:03
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:05
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'sharon'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'frey'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:50:18
Un-reviewed for Safety.	System	29 Jan 2021 18:39:11
DataPoint Un-verified.	System	29 Jan 2021 18:39:11
User entered empty.	System	29 Jan 2021 18:39:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 18:38:57
DataPoint Verified.		10 Nov 2020 20:30:50
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Nov 2020 15:26:54
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	10 Nov 2020 14:50:40
User entered empty.	System	10 Nov 2020 14:50:40
Reviewed for Safety.	System	10 Nov 2020 14:50:40
	(b) (4), (b) (6)	10 Nov 2020 14:50:29
DataPoint Verified.		09 Nov 2020 17:33:08
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:05
	(b) (4)	

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:50:20
Un-reviewed for Safety.	System	29 Jan 2021 18:39:11
DataPoint Un-verified.	System	29 Jan 2021 18:39:11
User entered empty.	System	29 Jan 2021 18:39:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 18:38:57
DataPoint Verified.		10 Nov 2020 20:30:52
User entered 'St. Louis' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Nov 2020 15:26:54
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 14:50:40
DataPoint Un-verified.	System	10 Nov 2020 14:50:40
User entered empty.	System	10 Nov 2020 14:50:40
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:50:29
DataPoint Verified.		09 Nov 2020 17:33:10
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:05
	(b) (4)	

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:08:14
Reviewed for Safety.		22 Sep 2020 14:03:41
User entered 'MO'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:50:21
Un-reviewed for Safety.	System	29 Jan 2021 18:39:11
DataPoint Un-verified.	System	29 Jan 2021 18:39:11
User entered empty.	System	29 Jan 2021 18:39:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 18:38:57
DataPoint Verified.		10 Nov 2020 20:30:54
User entered '63104' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Nov 2020 15:26:54
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 14:50:40
DataPoint Un-verified.	System	10 Nov 2020 14:50:40
User entered empty.	System	10 Nov 2020 14:50:40
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:50:29
DataPoint Verified.		09 Nov 2020 17:33:11
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:05
	(b) (4)	

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:15
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:06:53
User entered 'US'	System	22 Sep 2020 14:03:47

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
User entered '9'	(b) (4)	29 Jan 2021 18:39:11
User entered '8'	System	10 Nov 2020 14:50:40
User entered '7'	System	27 Oct 2020 12:24:34
User entered '6'	System	19 Oct 2020 19:46:30
User entered '5'	System	13 Oct 2020 14:20:46
User entered '4'	System	09 Oct 2020 13:26:20
User entered '3'	System	02 Oct 2020 12:14:25
User entered '2'	System	29 Sep 2020 13:07:01
User entered '1'	System	22 Sep 2020 14:03:47

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:13:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:47:05
User entered '19/Oct/2020 15:46'	System	19 Oct 2020 19:46:30

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:13:46

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.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	05 Nov 2020 21:47:07
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 12:24:26
User entered 'l'		19 Oct 2020 19:46:30

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:07:55
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'USA-US089-2020-MRNA-1273-P301000004'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:07:56
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'Yes (Y)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:07:58
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:00
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:01
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'Yes (Y)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:03
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:05
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'sharon'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'frey'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:50:18
Un-reviewed for Safety.	System	29 Jan 2021 18:39:11
DataPoint Un-verified.	System	29 Jan 2021 18:39:11
User entered empty.	System	29 Jan 2021 18:39:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 18:38:57
DataPoint Verified.		10 Nov 2020 20:30:50
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Nov 2020 15:26:54
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	10 Nov 2020 14:50:40
User entered empty.	System	10 Nov 2020 14:50:40
Reviewed for Safety.	System	10 Nov 2020 14:50:40
	(b) (4), (b) (6)	10 Nov 2020 14:50:29
DataPoint Verified.		09 Nov 2020 17:33:08
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:05
	(b) (4)	

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:50:20
Un-reviewed for Safety.	System	29 Jan 2021 18:39:11
DataPoint Un-verified.	System	29 Jan 2021 18:39:11
User entered empty.	System	29 Jan 2021 18:39:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 18:38:57
DataPoint Verified.		10 Nov 2020 20:30:52
User entered 'St. Louis' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Nov 2020 15:26:54
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 14:50:40
DataPoint Un-verified.	System	10 Nov 2020 14:50:40
User entered empty.	System	10 Nov 2020 14:50:40
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:50:29
DataPoint Verified.		09 Nov 2020 17:33:10
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:05
	(b) (4)	

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:14
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'MO'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:50:21
Un-reviewed for Safety.	System	29 Jan 2021 18:39:11
DataPoint Un-verified.	System	29 Jan 2021 18:39:11
User entered empty.	System	29 Jan 2021 18:39:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 18:38:57
DataPoint Verified.		10 Nov 2020 20:30:54
User entered '63104' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Nov 2020 15:26:54
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 14:50:40
DataPoint Un-verified.	System	10 Nov 2020 14:50:40
User entered empty.	System	10 Nov 2020 14:50:40
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:50:29
DataPoint Verified.		09 Nov 2020 17:33:11
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:05
	(b) (4)	

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:15
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:06:53
User entered 'US'	System	22 Sep 2020 14:03:47

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
User entered '9'	(b) (4)	29 Jan 2021 18:39:11
User entered '8'	System	10 Nov 2020 14:50:40
User entered '7'	System	27 Oct 2020 12:24:34
User entered '6'	System	19 Oct 2020 19:46:30
User entered '5'	System	13 Oct 2020 14:20:46
User entered '4'	System	09 Oct 2020 13:26:20
User entered '3'	System	02 Oct 2020 12:14:25
User entered '2'	System	29 Sep 2020 13:07:01
User entered '1'	System	22 Sep 2020 14:03:47

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 08:13:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:47:10
User entered '27/Oct/2020 08:24'	System	27 Oct 2020 12:24:34

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 08:13:46

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.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 14:50:29
DataPoint Verified.		05 Nov 2020 21:47:11
User entered 'l'		27 Oct 2020 12:24:34

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:07:55
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'USA-US089-2020-MRNA-1273-P301000004'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:07:56
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'Yes (Y)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:07:58
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:00
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:01
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'Yes (Y)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:03
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:05
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'sharon'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'frey'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:50:18
Un-reviewed for Safety.	System	29 Jan 2021 18:39:11
DataPoint Un-verified.	System	29 Jan 2021 18:39:11
User entered empty.	System	29 Jan 2021 18:39:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 18:38:57
DataPoint Verified.		10 Nov 2020 20:30:50
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Nov 2020 15:26:54
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	10 Nov 2020 14:50:40
User entered empty.	System	10 Nov 2020 14:50:40
Reviewed for Safety.	System	10 Nov 2020 14:50:40
	(b) (4), (b) (6)	10 Nov 2020 14:50:29
DataPoint Verified.		09 Nov 2020 17:33:08
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:05
	(b) (4)	

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:50:20
Un-reviewed for Safety.	System	29 Jan 2021 18:39:11
DataPoint Un-verified.	System	29 Jan 2021 18:39:11
User entered empty.	System	29 Jan 2021 18:39:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 18:38:57
DataPoint Verified.		10 Nov 2020 20:30:52
User entered 'St. Louis' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Nov 2020 15:26:54
Un-reviewed for Safety.	System	10 Nov 2020 14:50:40
DataPoint Un-verified.	System	10 Nov 2020 14:50:40
User entered empty.	System	10 Nov 2020 14:50:40
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:50:29
DataPoint Verified.		09 Nov 2020 17:33:10
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:05
	(b) (4)	

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:14
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'MO'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:50:21
Un-reviewed for Safety.	System	29 Jan 2021 18:39:11
DataPoint Un-verified.	System	29 Jan 2021 18:39:11
User entered empty.	System	29 Jan 2021 18:39:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 18:38:57
DataPoint Verified.		10 Nov 2020 20:30:54
User entered '63104' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Nov 2020 15:26:54
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 14:50:40
DataPoint Un-verified.	System	10 Nov 2020 14:50:40
User entered empty.	System	10 Nov 2020 14:50:40
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:50:29
DataPoint Verified.		09 Nov 2020 17:33:11
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:05
	(b) (4)	

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 16:08:15
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:06:53
User entered 'US'	System	22 Sep 2020 14:03:47

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
User entered '9'	(b) (4)	29 Jan 2021 18:39:11
User entered '8'	System	10 Nov 2020 14:50:40
User entered '7'	System	27 Oct 2020 12:24:34
User entered '6'	System	19 Oct 2020 19:46:30
User entered '5'	System	13 Oct 2020 14:20:46
User entered '4'	System	09 Oct 2020 13:26:20
User entered '3'	System	02 Oct 2020 12:14:25
User entered '2'	System	29 Sep 2020 13:07:01
User entered '1'	System	22 Sep 2020 14:03:47

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 08:13:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 13:47:07
User entered '10/Nov/2020 09:50'	System	10 Nov 2020 14:50:40

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 08:13:46

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.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
Reviewed for Safety.	(b) (4)	29 Jan 2021 18:38:57
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 13:47:15
User entered 'l'		10 Nov 2020 14:50:40

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:07:55
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'USA-US089-2020-MRNA-1273-P301000004'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:07:56
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'Yes (Y)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:07:58
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:00
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:01
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'Yes (Y)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:03
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:05
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'No (N)'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'sharon'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'frey'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:50:18
Un-reviewed for Safety.	System	29 Jan 2021 18:39:11
DataPoint Un-verified.	System	29 Jan 2021 18:39:11
User entered empty.	System	29 Jan 2021 18:39:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 18:38:57
DataPoint Verified.		10 Nov 2020 20:30:50
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Nov 2020 15:26:54
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	10 Nov 2020 14:50:40
User entered empty.	System	10 Nov 2020 14:50:40
Reviewed for Safety.	System	10 Nov 2020 14:50:40
	(b) (4), (b) (6)	10 Nov 2020 14:50:29
DataPoint Verified.		09 Nov 2020 17:33:08
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:05
	(b) (4)	

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:50:20
Un-reviewed for Safety.	System	29 Jan 2021 18:39:11
DataPoint Un-verified.	System	29 Jan 2021 18:39:11
User entered empty.	System	29 Jan 2021 18:39:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 18:38:57
DataPoint Verified.		10 Nov 2020 20:30:52
User entered 'St. Louis' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Nov 2020 15:26:54
Un-reviewed for Safety.	System	10 Nov 2020 14:50:40
DataPoint Un-verified.	System	10 Nov 2020 14:50:40
User entered empty.	System	10 Nov 2020 14:50:40
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:50:29
DataPoint Verified.		09 Nov 2020 17:33:10
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:05
	(b) (4)	

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:14
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:03:41
User entered 'MO'	System	22 Sep 2020 14:03:08

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:50:21
Un-reviewed for Safety.	System	29 Jan 2021 18:39:11
DataPoint Un-verified.	System	29 Jan 2021 18:39:11
User entered empty.	System	29 Jan 2021 18:39:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 18:38:57
DataPoint Verified.		10 Nov 2020 20:30:54
User entered '63104' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Nov 2020 15:26:54
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 14:50:40
DataPoint Un-verified.	System	10 Nov 2020 14:50:40
User entered empty.	System	10 Nov 2020 14:50:40
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:50:29
DataPoint Verified.		09 Nov 2020 17:33:11
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:05
	(b) (4)	

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4)	12 Oct 2020 16:08:15
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:06:53
User entered 'US'	System	22 Sep 2020 14:03:47

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
User entered '9'	(b) (4)	29 Jan 2021 18:39:11
User entered '8'	System	10 Nov 2020 14:50:40
User entered '7'	System	27 Oct 2020 12:24:34
User entered '6'	System	19 Oct 2020 19:46:30
User entered '5'	System	13 Oct 2020 14:20:46
User entered '4'	System	09 Oct 2020 13:26:20
User entered '3'	System	02 Oct 2020 12:14:25
User entered '2'	System	29 Sep 2020 13:07:01
User entered '1'	System	22 Sep 2020 14:03:47

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 08:13:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:49:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:51:42
User entered '29/Jan/2021 18:39'	System	29 Jan 2021 18:39:11

US3552331

Folder: SAE USA-US089-2020-MRNA-1273-P301000004

Form: Safety Report Form (9)

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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.

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