

US3732094 (Prod: eStudySite - La Mesa - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:29:56

All time stamps listed in this document are displayed in GMT

US3732094

Form: Participant Creation

Data signed: (b) (4) 24 Feb 2021 23:22:08

Generated On: 10 Jun 2021 09:29:56

Participant ID

US3732094

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

US3732094

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

Date of Birth (MMM yyyy)	(b) (6) 1950
Age	69
Age Units	YEARS
Age (Derived)	69
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 24 Feb 2021 23:22:09

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Date of Informed Consent (<i>dd MMM yyyy</i>)	19 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

Condition	CIPRO DRUG ALLERGY
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

Condition	ALCOHOL USE
Start date (dd MMM yyyy)	UN UNK 1968
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1968
Start Year (derived)	1968
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

Condition	MARIJUANA USE - INHALATION
Start date (dd MMM yyyy)	UN UNK 1968
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1968
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1968
Start Year (derived)	1968
Stop Month and Year (derived)	JAN 1968
Stop Year (derived)	1968

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

Condition	GANGLION CYST - LEFT FOOT
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1980
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	JAN 1980
Stop Year (derived)	1980

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

Condition	GANGLION CYST LEFT FOOT REMOVAL
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1980
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	JAN 1980
Stop Year (derived)	1980

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

Condition	NON-MIGRAINE HEADACHES
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3732094

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	19 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	10:11 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 10:11
Height (<i>xxx.x</i>)	179.8 cm
Weight (<i>xxx.x</i>)	83.9 kg
BMI (<i>xxx.x</i>)	25.95270 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 24 Feb 2021 23:22:09

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

What was the date of randomization? (dd MMM yyyy) 19 AUG 2020

What was the participant's randomization number? 186763

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) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

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) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 AUG 2020
Time of assessment (00:00-23:59)	10:11 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 10:11
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 AUG 2020
Time of assessment (00:00-23:59)	11:33 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 11:33
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

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: Exposure

Data signed: (b) (4) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 19 AUG 2020

What was the treatment time? (00:00-23:59) 11:02 (24 HR)

Treatment Date and Time (derived) 19 AUG 2020 11:02

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) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 AUG 2020
Collection time (00:00-23:59)	10:38 (24 HR)
Collection date and time (derived)	19 AUG 2020 10:38

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

Collection date (dd MMM yyyy)			19 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:35	19 AUG 2020 10:35
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

19 AUG 2020 11:37

PC Open Date & Time

19 AUG 2020 11:22

PC Close Date & Time

19 AUG 2020 13:52

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.4 °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	19 AUG 2020 16:34
PC Open Date & Time	19 AUG 2020 14:47
PC Close Date & Time	20 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

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

20 AUG 2020 16:41

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 12:01

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

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

22 AUG 2020 21:43

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 12:00

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 13:22

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

25 AUG 2020 15:12

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

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

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

19 AUG 2020 12:44

PC Open Date & Time

19 AUG 2020 11:22

PC Close Date & Time

19 AUG 2020 13:52

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 16:34

PC Open Date & Time

19 AUG 2020 14:47

PC Close Date & Time

20 AUG 2020 11:59

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 16:41

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 12:01

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 21:43

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 12:01

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 13:22

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 15:12

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 12:45
PC Open Date & Time	19 AUG 2020 11:22
PC Close Date & Time	19 AUG 2020 13:52

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 16:35
PC Open Date & Time	19 AUG 2020 14:47
PC Close Date & Time	20 AUG 2020 11:59

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:56

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 16:42
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:56

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 12:01
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:56

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 21:44
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

61 of 2138

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:56

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 12:01
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

63 of 2138

EAB) (1725)

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:56

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 13:23
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:56

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 15:12
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3732094

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 27 AUG 2020 05:59

PC Open Date & Time 26 AUG 2020 12:00

PC Close Date & Time 27 AUG 2020 11:59

US3732094

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	27 AUG 2020 05:59
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3732094

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732094

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732094

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732094

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732094

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732094

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732094

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 23:22:10

Generated On: 10 Jun 2021 09:29:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3732094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Feb 2021 23:22:10

Generated On: 10 Jun 2021 09:29:56

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 SEP 2020
Time of assessment (00:00-23:59)	09:05 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 09:05
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3732094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Feb 2021 23:22:10

Generated On: 10 Jun 2021 09:29:56

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	16 SEP 2020
Time of assessment (00:00-23:59)	10:25 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 10:25
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	95 mmHg
Diastolic Blood Pressure units	MMHG

US3732094

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 23:22:10

Generated On: 10 Jun 2021 09:29:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 SEP 2020

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

US3732094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 24 Feb 2021 23:22:10

Generated On: 10 Jun 2021 09:29:56

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 16 SEP 2020

What was the treatment time? (00:00-23:59) 09:55 (24 HR)

Treatment Date and Time (derived) 16 SEP 2020 09:55

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

US3732094

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 23:22:10

Generated On: 10 Jun 2021 09:29:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 SEP 2020
Collection time (00:00-23:59)	09:27 (24 HR)
Collection date and time (derived)	16 SEP 2020 09:27

US3732094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 24 Feb 2021 23:22:10

Generated On: 10 Jun 2021 09:29:56

Collection date (dd MMM yyyy)			16 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:18	16 SEP 2020 09:18
Nasopharyngeal Swab 2	No		

US3732094

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 23:22:10

Generated On: 10 Jun 2021 09:29:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 11:33

PC Open Date & Time

16 SEP 2020 10:15

PC Close Date & Time

16 SEP 2020 12:45

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °F

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

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

PC Time Stamp	16 SEP 2020 18:26
PC Open Date & Time	16 SEP 2020 13:40
PC Close Date & Time	17 SEP 2020 11:59

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

100.2 °F

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

Yes ☒

No ☐

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

To **TREAT** pain or fever that has already occurred

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

17 SEP 2020 16:03

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 12:15

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☒

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 19 SEP 2020 18:02

PC Open Date & Time 19 SEP 2020 12:00

PC Close Date & Time 20 SEP 2020 11:59

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 12:01

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☒

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 21 SEP 2020 17:18

PC Open Date & Time 21 SEP 2020 12:00

PC Close Date & Time 22 SEP 2020 11:59

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☒

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 22 SEP 2020 12:00

PC Open Date & Time 22 SEP 2020 12:00

PC Close Date & Time 23 SEP 2020 11:59

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 11:33

PC Open Date & Time

16 SEP 2020 10:15

PC Close Date & Time

16 SEP 2020 12:45

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 18:27

PC Open Date & Time

16 SEP 2020 13:40

PC Close Date & Time

17 SEP 2020 11:59

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 16:03

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 12:15

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 18:03

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 12:01

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 17:19

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 12:00

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 11:33
PC Open Date & Time	16 SEP 2020 10:15
PC Close Date & Time	16 SEP 2020 12:45

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some

interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 18:27
PC Open Date & Time	16 SEP 2020 13:40
PC Close Date & Time	17 SEP 2020 11:59

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☒

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:56

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 16:04
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:56

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 12:16
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:56

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 18:03
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:56

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 12:02
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:56

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 17:19
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:56

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 12:00
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3732094

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732094

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732094

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732094

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732094

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732094

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732094

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 23:22:10

Generated On: 10 Jun 2021 09:29:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3732094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Feb 2021 23:22:10

Generated On: 10 Jun 2021 09:29:56

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 OCT 2020
Time of assessment (00:00-23:59)	09:14 (24 HR)
Vital Signs Date and Time (derived)	20 OCT 2020 09:14
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3732094

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 23:22:10

Generated On: 10 Jun 2021 09:29:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 OCT 2020

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

US3732094

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 23:22:10

Generated On: 10 Jun 2021 09:29:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 OCT 2020
Collection time (00:00-23:59)	09:14 (24 HR)
Collection date and time (derived)	20 OCT 2020 09:14

US3732094

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 23:22:10

Generated On: 10 Jun 2021 09:29:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 OCT 2020 11:44:43

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3732094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 OCT 2020 12:01:13

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3732094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

05 NOV 2020 06:19:58

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3732094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 20:42:46

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 NOV 2020 13:22:34
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 14:41:52

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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

06 DEC 2020 12:00:24

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 DEC 2020 17:59:24

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 DEC 2020 16:55:30

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	25 DEC 2020 09:26:39
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 JAN 2021 11:28:16

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 JAN 2021 12:00:33

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 JAN 2021 09:55:57

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 159

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 JAN 2021 00:04:58

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 FEB 2021 22:49:20

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 FEB 2021 11:50:02
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 FEB 2021 07:40:10

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	27 FEB 2021 15:38:21
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	05 MAR 2021 00:04:21
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 MAR 2021 19:46:33

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 15:50:38

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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

26 MAR 2021 15:01:00

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 APR 2021 18:11:32

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 10:26:39

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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

16 APR 2021 06:17:12

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 APR 2021 05:32:38

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 01:50:41

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 299

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

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

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

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

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

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

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

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 313

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 JUL 2021 00:01
Patient Cloud Close Date & Time	20 JUL 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

Patient Cloud Open Date & Time	13 AUG 2021 00:01
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Patient Cloud Close Date & Time	17 AUG 2021 23:59
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US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 369

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 376

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 404

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

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

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

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

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

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

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

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 OCT 2021 00:01
Patient Cloud Close Date & Time	05 OCT 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

Patient Cloud Open Date & Time	08 OCT 2021 00:01
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Patient Cloud Close Date & Time	12 OCT 2021 23:59
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US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

Patient Cloud Open Date & Time	15 OCT 2021 00:01
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Patient Cloud Close Date & Time	19 OCT 2021 23:59
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US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

Patient Cloud Open Date & Time	22 OCT 2021 00:01
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Patient Cloud Close Date & Time	26 OCT 2021 23:59
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US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 NOV 2021 00:01
Patient Cloud Close Date & Time	30 NOV 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 502

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 572

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 684

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 JUL 2022 00:01
Patient Cloud Close Date & Time	12 JUL 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

Patient Cloud Open Date & Time	12 AUG 2022 00:01
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Patient Cloud Close Date & Time	16 AUG 2022 23:59
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US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3732094

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:29:56

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		27 FEB 2021 15:38:31

US3732094

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732094

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732094

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 31 Mar 2021 22:59:49

Generated On: 10 Jun 2021 09:29:56

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3732094

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732094

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732094

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732094

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732094

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732094

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 31 Mar 2021 22:59:49

Generated On: 10 Jun 2021 09:29:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3732094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 20:58:05

Generated On: 10 Jun 2021 09:29:56

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 MAR 2021
Time of assessment (00:00-23:59)	10:26 (24 HR)
Vital Signs Date and Time (derived)	15 MAR 2021 10:26
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	99 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3732094

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 31 Mar 2021 22:59:49

Generated On: 10 Jun 2021 09:29:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 MAR 2021

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

US3732094

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 31 Mar 2021 22:59:49

Generated On: 10 Jun 2021 09:29:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 MAR 2021
Collection time (00:00-23:59)	10:33 (24 HR)
Collection date and time (derived)	15 MAR 2021 10:33

US3732094

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 31 Mar 2021 22:59:49

Generated On: 10 Jun 2021 09:29:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732094

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3732094

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732094

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3732094

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:56

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3732094

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:29:56

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3732094

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

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 23:22:09

Generated On: 10 Jun 2021 09:29:56

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

Visit date (dd MMM yyyy)	14 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3732094

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

Form: Unblinding

Data signed: (b) (4) 31 Mar 2021 22:59:49

Generated On: 10 Jun 2021 09:29:56

Date of updated informed consent (dd MMM yyyy) 14 JAN 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 (dd MMM yyyy) 14 JAN 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 _____
Continuing with mRNA-1273 _____

US3732094

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 23:22:08

Generated On: 10 Jun 2021 09:29:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00-23:59)	11:54 (24 HR)
Collection date and time (derived)	14 JAN 2021 11:54

US3732094

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 31 Mar 2021 22:59:49

Generated On: 10 Jun 2021 09:29:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00 - 23:59)	11:49
Collection Date and Time (derived)	14 JAN 2021 11:49

US3732094

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 24 Feb 2021 23:22:08

Generated On: 10 Jun 2021 09:29:56

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3732094

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

AEID	USA-US102-2021-MRNA-1273-P30 1000003
Adverse event	SUPRAVENTRICULAR TACHYCARDIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	24 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	25 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	24 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	25 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

SUBJECT REPORTS OVERNIGHT HOSPITAL STAY FROM 24 DEC 2020 - 25 DEC 2020 TO RULE OUT CARDIAC ISSUE AS HE WENT TO THE ER FOR PALPITATIONS AND MILD CHEST TIGHTNESS ON 24 DEC 2020. DIAGNOSED WITH SUPRAVENTRICULAR TACHYCARDIA (RATE UNKNOWN). 09APR2021 MR NARRATIVE UPDATE - NEGATIVE COVID-19 MID-TURBINATE SWAB ON 24DEC2020. PLEASE SEE SENT EMAIL FOR REDACTED ED NOTES FOR LABS. DIAGNOSTIC TESTS DONE INCLUDE CHEST X-RAY (24DEC2020), HEAD AND NECK CTA (24DEC2020), ECHOCARDIOGRAM (25DEC2020), AND MULTIPLE ECGS (24-25DEC2020). CHEST X-RAY NORMAL. HEAD AND NECK CTA SHOWED NORMAL FINDINGS EXCEPT FOR A 3.6 CM LEFT THYROID CYST CAUSING DEVIATION OF THE LEFT CAROTID ARTERY AND JUGULAR VEIN. ECHO FINDINGS NORMAL. THE 4 ECGS FROM 24-25DEC2020 INDICATED EITHER NORMAL SINUS RHYTHM OR SINUS BRADYCARDIA. TREATMENT AT HOSPITAL CONSISTED OF A 5 MG METOPROLOL IV PUSH WITH DAILY 12.5 MG BID ORAL METOPROLOL FOLLOWING DISCHARGE.

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

US3732094

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

AEID

Adverse event

RIGHT SIDE PAPILLARY
THYROID CANCER

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)

15 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

26 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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US3732094

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 24 Feb 2021 23:22:08

Generated On: 10 Jun 2021 09:29:56

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

Yes ☒

No ☐

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

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 (1)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

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

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

Name of Medication SIMVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication NON-MIGRAINE HEADACHES

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1990	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication SUPRAVENTRICULAR
TACHYCARDIA

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

Name of Medication LIOTHYRONINE SODIUM

Prophylaxis Yes ☐
No ☒

Indication THYROID CANCER

Dose per administration 25

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) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☒
No ☐

Indication THYROID HORMONE THERAPY
STATUS POST TOTAL
THYROIDECTOMY

Dose per administration 137

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

Name of Medication METOPROLOL

Prophylaxis Yes ☒
No ☐

Indication SUPRAVENTRICULAR
TACHYCARDIA

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

Name of Medication SIMVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 40

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) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

Name of Medication DESYREL

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

Name of Medication NORVASC

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2011	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2011	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

Name of Medication LUNESTA

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3732094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 31 Mar 2021 22:59:49

Generated On: 10 Jun 2021 09:29:56

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3732094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
25 FEB 2021	BILATERAL TOTAL THYROIDECTOMY	Adverse Event	
24 DEC 2020	CHEST X-RAY	Diagnostic	
25 DEC 2020	ECHOCARDIOGRAM	Diagnostic	
24 DEC 2020	HEAD AND NECK CTA	Diagnostic	
24 DEC 2020	ECG	Diagnostic	
25 DEC 2020	ECG	Diagnostic	

US3732094

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:29:56

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3732094

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:29:56

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

SAEID	USA-US102-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

SAEID	USA-US102-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	20/JAN/2021 09:45
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

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

SAEID	USA-US102-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	24/MAR/2021 15:44
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

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

SAEID	USA-US102-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	06/APR/2021 11:01
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

SAEID	USA-US102-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	12/APR/2021 14:10
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

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 22:19:52

Generated On: 10 Jun 2021 09:29:56

SAEID	USA-US102-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	26/APR/2021 06:20
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

Audit

US3732094 (Prod: eStudySite - La Mesa - PPDS)

US3732094

Form: Participant Creation

Generated On: 10 Jun 2021 09:29:56

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'US3732094'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	19 Aug 2020 17:29:47

US3732094

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:29:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	(b) (4) Lauren Arnett (b) (4)	21 Aug 2020 02:12:23

US3732094

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '19 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 17:29:49

US3732094

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Clinic (Clinic)'	Lauren Arnett (b) (4)	21 Aug 2020 02:12:23

US3732094

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:29:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'SCRN'	System	21 Aug 2020 02:12:23

US3732094

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered (b) (6) 1950'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 17:29:51

US3732094

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:56

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '69'	Lauren Arnett (b) (4)	21 Aug 2020 02:13:44

US3732094

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:56

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'YEARS'	System	21 Aug 2020 02:13:44

US3732094

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:56

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered '69'	System	19 Aug 2020 18:04:47

US3732094

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:56

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Male (M)'	Lauren Arnett (b) (4)	21 Aug 2020 02:13:44

US3732094

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:56

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Lauren Arnett (b) (4)	21 Aug 2020 02:13:44

US3732094

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:56

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'I'	Lauren Arnett (b) (4)	21 Aug 2020 02:13:44

US3732094

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:56

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 02:13:44

US3732094

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:56

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 02:13:44

US3732094

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:56

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 02:13:44

US3732094

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:56

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 02:13:44

US3732094

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:56

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 02:13:44

US3732094

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:56

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	(b) (4) Lauren Arnett (b) (4)	21 Aug 2020 02:13:44

US3732094

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:56

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 02:13:44

US3732094

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:56

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 02:13:44

US3732094

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '19 Aug 2020'	Lauren Arnett (b) (4)	19 Aug 2020 18:04:47

US3732094

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'Aug 2020'	System	19 Aug 2020 18:04:47

US3732094

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered '2020'	System	19 Aug 2020 18:04:47

US3732094

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:56

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Amendment 2 (2)'	Lauren Arnett (b) (4)	19 Aug 2020 18:04:47

US3732094

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	19 Aug 2020 18:04:47

US3732094

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Lauren Arnett (b) (4)	19 Aug 2020 18:04:47

US3732094

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:56

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Lauren Arnett (b) (4)	19 Aug 2020 18:04:47

US3732094

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:56

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'No (N)'	Lauren Arnett (b) (4)	19 Aug 2020 18:04:47

US3732094

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:56

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 17:29:49

US3732094

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:56

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'I'	System	19 Aug 2020 18:04:53

US3732094

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	19 Aug 2020 18:04:53

US3732094

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:29:56

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	21 Aug 2020 02:14:06

US3732094

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
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.	(b) (4) Coder Import (b) (4)	19 Sep 2020 23:31:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Sep 2020 23:31:41
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)	25 Aug 2020 11:00:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 11:00:45
Data point term sent to Coder	System	21 Aug 2020 02:14:30
User entered 'cipro drug allergy'	Lauren Arnett (b) (4)	21 Aug 2020 02:14:21

US3732094

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'un UNK 1990'	Lauren Arnett (b) (4)	21 Aug 2020 02:14:21

US3732094

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 02:14:21

US3732094

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	21 Aug 2020 02:14:21

US3732094

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Lauren Arnett (b) (4)	21 Aug 2020 02:14:21

US3732094

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 02:14:21

US3732094

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'Jan 1990'	System	21 Aug 2020 02:14:21

US3732094

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered '1990'	System	21 Aug 2020 02:14:21

US3732094

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered empty.	System	21 Aug 2020 02:14:21

US3732094

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered empty.	System	21 Aug 2020 02:14:21

US3732094

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:29:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness bilateral, LLT: Hearing loss bilateral - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 02:17:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 02:17:09
Data point term sent to Coder	System	21 Aug 2020 02:15:31
User entered 'bilateral hearing loss'	Lauren Arnett (b) (4)	21 Aug 2020 02:14:32

US3732094

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'un UNK 2015'	Lauren Arnett (b) (4)	21 Aug 2020 02:14:32

US3732094

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:29:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 02:14:32

US3732094

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:29:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	21 Aug 2020 02:14:32

US3732094

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Lauren Arnett (b) (4)	21 Aug 2020 02:14:32

US3732094

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:29:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 02:14:32

US3732094

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'Jan 2015'	System	21 Aug 2020 02:14:32

US3732094

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered '2015'	System	21 Aug 2020 02:14:32

US3732094

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered empty.	System	21 Aug 2020 02:14:32

US3732094

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered empty.	System	21 Aug 2020 02:14:32

US3732094

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:29:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Presbyopia, LLT: Presbyopia - version MedDRA\\23.0.	(b) (4)	21 Aug 2020 02:17:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 02:17:08
Data point term sent to Coder	System	21 Aug 2020 02:15:31
User entered 'presbyopia'	Lauren Arnett (b) (4)	21 Aug 2020 02:14:47

US3732094

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'un UNK 2010'	Lauren Arnett (b) (4)	21 Aug 2020 02:14:47

US3732094

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:29:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 02:14:47

US3732094

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:29:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	21 Aug 2020 02:14:47

US3732094

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Lauren Arnett (b) (4)	21 Aug 2020 02:14:47

US3732094

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:29:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 02:14:47

US3732094

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'Jan 2010'	System	21 Aug 2020 02:14:47

US3732094

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered '2010'	System	21 Aug 2020 02:14:47

US3732094

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered empty.	System	21 Aug 2020 02:14:47

US3732094

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered empty.	System	21 Aug 2020 02:14:47

US3732094

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:29:56

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User coded data point as SOC: Vascular disorders, HLTG: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 02:17:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 02:17:08
Data point term sent to Coder	System	21 Aug 2020 02:15:31
User entered 'hypertension'	Lauren Arnett (b) (4)	21 Aug 2020 02:14:58

US3732094

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'un UNK 2015'	Lauren Arnett (b) (4)	21 Aug 2020 02:14:58

US3732094

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:29:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 02:14:58

US3732094

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:29:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	21 Aug 2020 02:14:58

US3732094

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Lauren Arnett (b) (4)	21 Aug 2020 02:14:58

US3732094

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:29:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 02:14:58

US3732094

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'Jan 2015'	System	21 Aug 2020 02:14:58

US3732094

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered '2015'	System	21 Aug 2020 02:14:58

US3732094

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered empty.	System	21 Aug 2020 02:14:58

US3732094

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered empty.	System	21 Aug 2020 02:14:58

US3732094

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:29:56

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	21 Aug 2020 02:17:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 02:17:08
Data point term sent to Coder	System	21 Aug 2020 02:15:32
User entered 'prostate cancer'	Lauren Arnett (b) (4)	21 Aug 2020 02:15:24
	(b) (4)	

US3732094

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'un UNK 2015'	Lauren Arnett (b) (4)	21 Aug 2020 02:15:24

US3732094

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:29:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 02:15:24

US3732094

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:29:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	21 Aug 2020 02:15:24

US3732094

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Lauren Arnett (b) (4)	21 Aug 2020 02:15:24

US3732094

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:29:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 02:15:24

US3732094

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'Jan 2015'	System	21 Aug 2020 02:15:24

US3732094

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered '2015'	System	21 Aug 2020 02:15:24

US3732094

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered empty.	System	21 Aug 2020 02:15:24

US3732094

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered empty.	System	21 Aug 2020 02:15:24

US3732094

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:29:56

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User coded data point as SOC: Gastrointestinal disorders, HLG: Abdominal hernias and other abdominal wall conditions, HLT: Abdominal hernias NEC, PT: Abdominal hernia, LLT: Abdominal hernia - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 02:17:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 02:17:09
Data point term sent to Coder	System	21 Aug 2020 02:16:33
User entered 'abdominal hernia'	Lauren Arnett (b) (4)	21 Aug 2020 02:15:45

US3732094

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'un UNK 1995'	Lauren Arnett (b) (4)	21 Aug 2020 02:15:45

US3732094

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:29:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 02:15:45

US3732094

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:29:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 02:15:45

US3732094

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'un UNK 1995'	Lauren Arnett (b) (4)	21 Aug 2020 02:15:45

US3732094

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:29:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 02:15:45

US3732094

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'Jan 1995'	System	21 Aug 2020 02:15:45

US3732094

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered '1995'	System	21 Aug 2020 02:15:45

US3732094

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'Jan 1995'	System	21 Aug 2020 02:15:45

US3732094

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered '1995'	System	21 Aug 2020 02:15:45

US3732094

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:29:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User coded data point as SOC: Surgical and medical procedures, HLG: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Abdominal hernia repair, LLT: Abdominal hernia repair - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 02:17:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 02:17:09
Data point term sent to Coder	System	21 Aug 2020 02:16:32
User entered 'abdominal hernia repair'	Lauren Arnett (b) (4)	21 Aug 2020 02:16:01

US3732094

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'un UNK 1995'	Lauren Arnett (b) (4)	21 Aug 2020 02:16:01

US3732094

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:29:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 02:16:01

US3732094

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:29:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'No (N)'	Lauren Arnett (b) (4)	21 Aug 2020 02:16:01

US3732094

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'un UNK 1995'	Lauren Arnett (b) (4)	21 Aug 2020 02:16:01

US3732094

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:29:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 02:16:01

US3732094

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'Jan 1995'	System	21 Aug 2020 02:16:01

US3732094

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered '1995'	System	21 Aug 2020 02:16:01

US3732094

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'Jan 1995'	System	21 Aug 2020 02:16:01

US3732094

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered '1995'	System	21 Aug 2020 02:16:01

US3732094

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:29:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User coded data point as SOC: Social circumstances, HLT: Lifestyle issues, HLT: Alcohol product use, PT: Alcohol use, LLT: Alcohol use - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 02:19:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 02:19:09
Data point term sent to Coder	System	21 Aug 2020 02:17:33
User entered 'alcohol use'	Lauren Arnett (b) (4)	21 Aug 2020 02:16:35

US3732094

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'un UNK 1968'	Lauren Arnett (b) (4)	21 Aug 2020 02:16:35

US3732094

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:29:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 02:16:35

US3732094

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:29:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	21 Aug 2020 02:16:35

US3732094

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Lauren Arnett (b) (4)	21 Aug 2020 02:16:35

US3732094

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:29:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 02:16:35

US3732094

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'Jan 1968'	System	21 Aug 2020 02:16:35

US3732094

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered '1968'	System	21 Aug 2020 02:16:35

US3732094

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered empty.	System	21 Aug 2020 02:16:35

US3732094

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered empty.	System	21 Aug 2020 02:16:35

US3732094

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:29:56

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User coded data point as SOC: Social circumstances, HLT: Lifestyle issues, HLT: Social issues NEC, PT: Substance use, LLT: Marijuana use - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 07:24:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 07:24:41
Data point term sent to Coder	System	21 Aug 2020 02:17:33
User entered 'marijuana use - inhalation'	Lauren Arnett (b) (4)	21 Aug 2020 02:16:57

US3732094

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'un UNK 1968'	Lauren Arnett (b) (4)	21 Aug 2020 02:16:57

US3732094

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:29:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 02:16:57

US3732094

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:29:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'No (N)'	Lauren Arnett (b) (4)	21 Aug 2020 02:16:57

US3732094

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'un UNK 1968'	Lauren Arnett (b) (4)	21 Aug 2020 02:16:57

US3732094

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:29:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 02:16:57

US3732094

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:29:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'Jan 1968'	System	21 Aug 2020 02:16:57

US3732094

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:29:56

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered '1968'	System	21 Aug 2020 02:16:57

US3732094

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:29:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'Jan 1968'	System	21 Aug 2020 02:16:57

US3732094

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:29:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered '1968'	System	21 Aug 2020 02:16:57

US3732094

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:29:56

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Synovial and bursal disorders, HLT: Synovial disorders, PT: Synovial cyst, LLT: Ganglion cyst - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 05:15:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 05:15:20
Data point term sent to Coder	System	21 Aug 2020 02:17:36
User entered 'ganglion cyst - left foot'	Lauren Arnett (b) (4)	21 Aug 2020 02:17:25

US3732094

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:29:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'un UNK 1980'	Lauren Arnett (b) (4)	21 Aug 2020 02:17:25

US3732094

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:29:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 02:17:25

US3732094

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:29:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'No (N)'	Lauren Arnett (b) (4)	21 Aug 2020 02:17:25

US3732094

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:29:56

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'un UNK 1980'	Lauren Arnett (b) (4)	21 Aug 2020 02:17:25

US3732094

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:29:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 02:17:25

US3732094

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:29:56

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'Jan 1980'	System	21 Aug 2020 02:17:25

US3732094

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:29:56

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered '1980'	System	21 Aug 2020 02:17:25

US3732094

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:29:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'Jan 1980'	System	21 Aug 2020 02:17:25

US3732094

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:29:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered '1980'	System	21 Aug 2020 02:17:25

US3732094

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:29:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Synovial cyst removal, LLT: Ganglion removal - version MedDRA\\23.0.	Coder Import (b) (4)	23 Aug 2020 20:48:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Aug 2020 20:48:47
Data point term sent to Coder	System	21 Aug 2020 02:18:36
User entered 'ganglion cyst left foot removal'	Lauren Arnett (b) (4)	21 Aug 2020 02:18:07

US3732094

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:29:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'un UNK 1980'	Lauren Arnett (b) (4)	21 Aug 2020 02:18:07

US3732094

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:29:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 02:18:07

US3732094

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:29:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'No (N)'	Lauren Arnett (b) (4)	21 Aug 2020 02:18:07

US3732094

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:29:56

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'un UNK 1980'	Lauren Arnett (b) (4)	21 Aug 2020 02:18:07

US3732094

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:29:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 02:18:07

US3732094

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:29:56

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'Jan 1980'	System	21 Aug 2020 02:18:07

US3732094

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:29:56

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered '1980'	System	21 Aug 2020 02:18:07

US3732094

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:29:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'Jan 1980'	System	21 Aug 2020 02:18:07

US3732094

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:29:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered '1980'	System	21 Aug 2020 02:18:07

US3732094

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:29:56

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	22 Aug 2020 23:03:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 23:03:16
Data point term sent to Coder	System	22 Aug 2020 23:01:59
User entered 'hypercholesterolemia'	Lauren Arnett (b) (4)	22 Aug 2020 23:01:36
	(b) (4)	

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Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:29:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'un UNK 1990'	Lauren Arnett (b) (4)	22 Aug 2020 23:01:36

US3732094

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:29:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	22 Aug 2020 23:01:36

US3732094

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:29:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	22 Aug 2020 23:01:36

US3732094

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:29:56

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Lauren Arnett (b) (4)	22 Aug 2020 23:01:36

US3732094

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:29:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	22 Aug 2020 23:01:36

US3732094

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:29:56

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'Jan 1990'	System	22 Aug 2020 23:01:36

US3732094

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:29:56

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered '1990'	System	22 Aug 2020 23:01:36

US3732094

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:29:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered empty.	System	22 Aug 2020 23:01:36

US3732094

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:29:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered empty.	System	22 Aug 2020 23:01:36

US3732094

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:29:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
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)	25 Sep 2020 17:07:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 17:07:49
Data point term sent to Coder	System	25 Sep 2020 16:47:13
User entered 'non-migraine headaches'	Lauren Arnett (b) (4)	25 Sep 2020 16:46:26

US3732094

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:29:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'un UNK 1990'	Lauren Arnett (b) (4)	25 Sep 2020 16:46:26

US3732094

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:29:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	25 Sep 2020 16:46:26

US3732094

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:29:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	25 Sep 2020 16:46:26

US3732094

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:29:56

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Lauren Arnett (b) (4)	25 Sep 2020 16:46:26

US3732094

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:29:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	25 Sep 2020 16:46:26

US3732094

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:29:56

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'Jan 1990'	System	25 Sep 2020 16:46:26

US3732094

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:29:56

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered '1990'	System	25 Sep 2020 16:46:26

US3732094

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:29:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered empty.	System	25 Sep 2020 16:46:26

US3732094

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:29:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered empty.	System	25 Sep 2020 16:46:26

US3732094

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:29:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 18:16:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 18:16:52
Data point term sent to Coder	System	23 Apr 2021 18:15:47
User entered 'INSOMNIA'	(b) (4), (b) (6)	23 Apr 2021 18:15:32

US3732094

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:29:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
Data hard locked.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'UN UNK 2019'		23 Apr 2021 18:15:32

US3732094

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:29:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
Data hard locked.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered '0'		23 Apr 2021 18:15:32

US3732094

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:29:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
Data hard locked.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'Yes (Y)'		23 Apr 2021 18:15:32

US3732094

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:29:56

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
Data hard locked.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered empty.		23 Apr 2021 18:15:32

US3732094

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:29:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
Data hard locked.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered '0'		23 Apr 2021 18:15:32

US3732094

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:29:56

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'Jan 2019'	System	23 Apr 2021 18:15:32

US3732094

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:29:56

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered '2019'	System	23 Apr 2021 18:15:32

US3732094

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:29:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered empty.	System	23 Apr 2021 18:15:32

US3732094

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:29:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:05:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered empty.	System	23 Apr 2021 18:15:32

US3732094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	21 Aug 2020 02:19:21

US3732094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '19 Aug 2020'	Lauren Arnett (b) (4)	21 Aug 2020 02:19:21

US3732094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '10:11'	Lauren Arnett (b) (4)	21 Aug 2020 02:19:21

US3732094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered '19 Aug 2020 10:11'	System	21 Aug 2020 02:19:21

US3732094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '179.8' cm	(b) (4) Lauren Arnett (b) (4)	21 Aug 2020 02:19:21
DataPoint set to visible.	(b) (4) System	19 Aug 2020 18:04:53

US3732094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '83.9' kg	(b) (4) Lauren Arnett (b) (4)	21 Aug 2020 02:19:21
DataPoint set to visible.	(b) (4) System	19 Aug 2020 18:04:53

US3732094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
Amendment Manager: User entered '25.95270'	System	17 Sep 2020 00:14:23
User entered '26.0'	System	21 Aug 2020 02:19:21
DataPoint set to visible.	System	19 Aug 2020 18:04:53

US3732094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'kg/m2'	System	21 Aug 2020 02:19:21
DataPoint set to visible.	System	19 Aug 2020 18:04:53

US3732094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	27 Aug 2020 16:38:49
User entered '98.0' F	Lauren Arnett (b) (4)	21 Aug 2020 02:19:21
	(b) (4)	

US3732094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty; reason for change Data Entry Error	Lauren Arnett (b) (4)	27 Aug 2020 16:38:49
User entered 'Oral (Oral)'	Lauren Arnett (b) (4)	21 Aug 2020 02:19:21

US3732094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Lauren Arnett (b) (4)	21 Aug 2020 02:19:21

US3732094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	27 Aug 2020 16:38:49
User entered '62'	Lauren Arnett (b) (4)	21 Aug 2020 02:19:21
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'bpm'	System	21 Aug 2020 02:19:21

US3732094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	27 Aug 2020 16:38:49
User entered '14'	Lauren Arnett (b) (4)	21 Aug 2020 02:19:21
	(b) (4)	

US3732094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'breaths/min'	System	21 Aug 2020 02:19:21

US3732094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	27 Aug 2020 16:38:49
User entered '144'	Lauren Arnett (b) (4)	21 Aug 2020 02:19:21
	(b) (4)	

US3732094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'mmHg'	System	21 Aug 2020 02:19:21

US3732094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	27 Aug 2020 16:38:49
User entered '92'	Lauren Arnett (b) (4)	21 Aug 2020 02:19:21
	(b) (4)	

US3732094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'mmHg'	System	21 Aug 2020 02:19:21

US3732094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 05:33:09

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 05:33:09

US3732094

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	21 Aug 2020 02:19:36

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Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '19 Aug 2020'	Lauren Arnett (b) (4)	21 Aug 2020 02:19:36

US3732094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:56

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4)	21 Aug 2020 02:19:58

US3732094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:56

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 02:19:58

US3732094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:56

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Lauren Arnett (b) (4)	27 Aug 2020 16:41:14
User entered 'No (N)'	Lauren Arnett (b) (4)	21 Aug 2020 02:19:58

US3732094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:56

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)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'No (N)'	Lauren Arnett (b) (4)	21 Aug 2020 02:19:58

US3732094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:56

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'No (N)'	Lauren Arnett (b) (4)	21 Aug 2020 02:19:58

US3732094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:56

[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)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'No (N)'	Lauren Arnett (b) (4)	21 Aug 2020 02:19:58

US3732094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:56

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)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'No (N)'	Lauren Arnett (b) (4)	21 Aug 2020 02:19:58

US3732094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:56

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)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'No (N)'	Lauren Arnett (b) (4)	21 Aug 2020 02:19:58

US3732094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:56

[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)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'No (N)'	Lauren Arnett (b) (4)	21 Aug 2020 02:19:58

US3732094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:56

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)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'No (N)'	Lauren Arnett (b) (4)	21 Aug 2020 02:19:58

US3732094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:56

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)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'No (N)'	Lauren Arnett (b) (4)	21 Aug 2020 02:19:58

US3732094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:56

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'No (N)'	Lauren Arnett (b) (4)	21 Aug 2020 02:19:58

US3732094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:56

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Lauren Arnett (b) (4)	21 Aug 2020 02:19:58

US3732094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:56

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 02:19:58

US3732094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:56

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 02:19:58

US3732094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:56

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)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 02:19:58

US3732094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:56

[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)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	(b) (4) Lauren Arnett (b) (4)	21 Aug 2020 02:19:58

US3732094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:56

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)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 02:19:58

US3732094

Folder: Screening

Form: Risk of Exposure

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[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'I'	Lauren Arnett (b) (4)	21 Aug 2020 02:19:58

US3732094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:56

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 02:19:58

US3732094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:56

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Lauren Arnett (b) (4)	21 Aug 2020 02:19:58

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:29:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	21 Aug 2020 02:20:24

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:29:56

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '19 Aug 2020'	Lauren Arnett (b) (4)	21 Aug 2020 02:20:24

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:29:56

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Clinic (Clinic)'	Lauren Arnett (b) (4)	21 Aug 2020 02:20:24

US3732094

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:29:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'VISIT1'	System	21 Aug 2020 02:20:24

US3732094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:56

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '19 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 17:30:10

US3732094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:56

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:37:37
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:37:37
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 17:30:10
User entered '186763' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 17:30:10

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:56

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 17:30:10

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:56

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)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User closed query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4)	(b) (4), (b) (6)
Query 'PER CDM: Please complete this section of the form.' answered with 'complete ' (Site from DM).	Lauren Arnett (b) (4)	10 Sep 2020 17:46:59
User entered 'No (N)'	(b) (4)	10 Sep 2020 16:38:17
	Lauren Arnett (b) (4)	10 Sep 2020 16:38:07
	(b) (4)	(b) (4), (b) (6)
User opened query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 10:18:54

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:56

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)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'No (N)'	Lauren Arnett (b) (4)	10 Sep 2020 16:38:07

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:56

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'No (N)'	Lauren Arnett (b) (4)	10 Sep 2020 16:38:07

US3732094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:56

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'No (N)'	Lauren Arnett (b) (4)	10 Sep 2020 16:38:07

US3732094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:56

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'No (N)'	Lauren Arnett (b) (4)	10 Sep 2020 16:38:07

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:56

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:35:59
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:33:46

US3732094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:56

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 14:23:33
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' answered with 'updated' (Site from DM).	Lauren Arnett (b) (4)	25 Sep 2020 16:43:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 16:43:41
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 14:05:21
User entered empty; reason for change Data Entry Error	Lauren Arnett (b) (4)	27 Aug 2020 16:38:26
User entered '179.8' cm	Lauren Arnett (b) (4)	21 Aug 2020 02:21:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:56

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 16:43:41
User entered empty; reason for change Data Entry Error	Lauren Arnett (b) (4)	27 Aug 2020 16:38:26
User entered '83.9' kg	Lauren Arnett (b) (4)	21 Aug 2020 02:21:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:56

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 14:23:33
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' answered with 'updated' (Site from DM).	Lauren Arnett (b) (4)	25 Sep 2020 16:43:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 16:43:41
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 14:05:21
User entered empty; reason for change Data Entry Error	Lauren Arnett (b) (4)	27 Aug 2020 16:38:26
User entered '179.8' cm	Lauren Arnett (b) (4)	21 Aug 2020 02:21:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:56

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Lauren Arnett (b) (4)	25 Sep 2020 16:43:41
User entered empty; reason for change Data Entry Error	(b) (4) Lauren Arnett (b) (4)	27 Aug 2020 16:38:26
User entered '83.9' kg	(b) (4) Lauren Arnett (b) (4)	21 Aug 2020 02:21:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User accepted default value 'Pre-Dose (PREDOSE)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 02:21:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Lauren Arnett (b) (4)	27 Aug 2020 16:38:26
User entered 'No (N)' reason for change: Data Entry Error	Lauren Arnett (b) (4)	21 Aug 2020 02:22:03
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	21 Aug 2020 02:21:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '19 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Lauren Arnett (b) (4)	27 Aug 2020 16:38:26
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
	System	21 Aug 2020 02:22:03
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 02:21:54
User entered empty.	Lauren Arnett (b) (4)	21 Aug 2020 02:21:54
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '10:11' reason for change: Data Entry Error	Lauren Arnett (b) (4)	27 Aug 2020 16:38:26
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 02:22:03
Query 'Data is required. Please provide.' answered by System data change (Site from System).		21 Aug 2020 02:22:03
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 02:21:54
User entered empty.	Lauren Arnett (b) (4)	21 Aug 2020 02:21:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered '19 Aug 2020 10:11'	System	27 Aug 2020 16:38:26
User entered empty.	System	21 Aug 2020 02:21:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '98.0' F reason for change: Data Entry Error	Lauren Arnett (b) (4)	27 Aug 2020 16:38:26
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 02:22:03
Query 'Data is required. Please provide.' answered by System data change (Site from System).		21 Aug 2020 02:22:03
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 02:21:54
User entered empty.	Lauren Arnett (b) (4)	21 Aug 2020 02:21:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Oral (Oral)' reason for change: Data Entry Error	Lauren Arnett (b) (4)	27 Aug 2020 16:38:26
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 02:22:03
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 02:21:54
User entered empty.	Lauren Arnett (b) (4)	21 Aug 2020 02:21:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Lauren Arnett (b) (4)	21 Aug 2020 02:21:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '62' reason for change: Data Entry Error	Lauren Arnett (b) (4)	27 Aug 2020 16:38:26
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 02:22:03
Query 'Data is required. Please provide.' answered by System data change (Site from System).		21 Aug 2020 02:22:03
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 02:21:54
User entered empty.	Lauren Arnett (b) (4)	21 Aug 2020 02:21:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'bpm'	System	27 Aug 2020 16:38:26
User entered empty.	System	21 Aug 2020 02:21:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '14' reason for change: Data Entry Error	Lauren Arnett (b) (4)	27 Aug 2020 16:38:26
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 02:22:03
Query 'Data is required. Please provide.' answered by System data change (Site from System).		21 Aug 2020 02:22:03
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 02:21:54
User entered empty.	Lauren Arnett (b) (4)	21 Aug 2020 02:21:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'breaths/min'	System	27 Aug 2020 16:38:26
User entered empty.	System	21 Aug 2020 02:21:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '144' reason for change: Data Entry Error	Lauren Arnett (b) (4)	27 Aug 2020 16:38:26
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 02:22:03
Query 'Data is required. Please provide.' answered by System data change (Site from System).		21 Aug 2020 02:22:03
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 02:21:54
User entered empty.	Lauren Arnett (b) (4)	21 Aug 2020 02:21:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'mmHg'	System	27 Aug 2020 16:38:26
User entered empty.	System	21 Aug 2020 02:21:54

US3732094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '92' reason for change: Data Entry Error	Lauren Arnett (b) (4)	27 Aug 2020 16:38:26
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 02:22:03
Query 'Data is required. Please provide.' answered by System data change (Site from System).		21 Aug 2020 02:22:03
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 02:21:54
User entered empty.	Lauren Arnett (b) (4)	21 Aug 2020 02:21:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'mmHg'	System	27 Aug 2020 16:38:26
User entered empty.	System	21 Aug 2020 02:21:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:56

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 14:23:33
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' answered with 'updated' (Site from DM).	Lauren Arnett (b) (4)	25 Sep 2020 16:43:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 16:43:41
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 14:05:21
User entered empty; reason for change Data Entry Error	Lauren Arnett (b) (4)	27 Aug 2020 16:38:26
User entered '179.8' cm	Lauren Arnett (b) (4)	21 Aug 2020 02:21:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:56

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Lauren Arnett (b) (4)	25 Sep 2020 16:43:41
User entered empty; reason for change Data Entry Error	(b) (4) Lauren Arnett (b) (4)	27 Aug 2020 16:38:26
User entered '83.9' kg	(b) (4) Lauren Arnett (b) (4)	21 Aug 2020 02:21:54

US3732094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User accepted default value 'Post-Dose (POSTDOSE)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 02:21:54

US3732094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:56

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 02:22:03
User entered 'Yes (Y)' reason for change: Data Entry Error	Lauren Arnett (b) (4)	21 Aug 2020 02:22:03
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 02:21:54
User entered 'No (N)'	Lauren Arnett (b) (4)	21 Aug 2020 02:21:54
	(b) (4)	

US3732094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '19 Aug 2020'	Lauren Arnett (b) (4)	21 Aug 2020 02:21:54

US3732094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System (b) (4)	21 Aug 2020 05:37:33
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'correct as is' (Site from System).	Lauren Arnett (b) (4)	21 Aug 2020 02:22:14
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	21 Aug 2020 02:21:54
User entered '11:33'	Lauren Arnett (b) (4)	21 Aug 2020 02:21:54

US3732094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered '19 Aug 2020 11:33'	System	21 Aug 2020 02:21:54

US3732094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '97.7' F	Lauren Arnett (b) (4)	21 Aug 2020 02:21:54

US3732094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Oral (Oral)'	Lauren Arnett (b) (4)	21 Aug 2020 02:21:54

US3732094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Lauren Arnett (b) (4)	21 Aug 2020 02:21:54

US3732094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '58'	Lauren Arnett (b) (4)	21 Aug 2020 02:21:54

US3732094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'bpm'	System	21 Aug 2020 02:21:54

US3732094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '18'	Lauren Arnett (b) (4)	21 Aug 2020 02:21:54

US3732094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'breaths/min'	System	21 Aug 2020 02:21:54

US3732094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '145'	Lauren Arnett (b) (4)	21 Aug 2020 02:21:54

US3732094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'mmHg'	System	21 Aug 2020 02:21:54

US3732094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '93'	Lauren Arnett (b) (4)	21 Aug 2020 02:21:54

US3732094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'mmHg'	System	21 Aug 2020 02:21:54

US3732094

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'No (N)' reason for change: Data Entry Error	Lauren Arnett (b) (4)	21 Aug 2020 02:22:31
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	21 Aug 2020 02:22:25

US3732094

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User closed query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 02:22:31
User opened query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	21 Aug 2020 02:22:25
User entered empty.	Lauren Arnett (b) (4)	21 Aug 2020 02:22:25
	(b) (4)	

US3732094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:56

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	19 Aug 2020 18:05:17

US3732094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:56

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Lauren Arnett (b) (4)	19 Aug 2020 18:05:17

US3732094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:56

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 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Lauren Arnett (b) (4)	19 Aug 2020 18:05:17

US3732094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:56

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'MRNA-1273 OR PLACEBO'	System	19 Aug 2020 18:05:17

US3732094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:56

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '19 Aug 2020'	Lauren Arnett (b) (4)	19 Aug 2020 18:05:17

US3732094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:56

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '11:02'	Lauren Arnett (b) (4)	19 Aug 2020 18:05:17

US3732094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:56

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered '19 Aug 2020 11:02'	System	19 Aug 2020 18:05:17

US3732094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:56

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Left Arm (LEFT ARM)'	Lauren Arnett (b) (4)	19 Aug 2020 18:05:17

US3732094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:56

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'ONCE'	System	19 Aug 2020 18:05:17

US3732094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:56

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'INTRAMUSCULAR'	System	19 Aug 2020 18:05:17

US3732094

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	21 Aug 2020 02:23:24

US3732094

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:56

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '19 Aug 2020'	Lauren Arnett (b) (4)	21 Aug 2020 02:23:24

US3732094

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:56

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '10:38'	Lauren Arnett (b) (4)	21 Aug 2020 02:23:24

US3732094

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered '19 Aug 2020 10:38'	System	21 Aug 2020 02:23:24

US3732094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:29:56

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '19 Aug 2020'	Lauren Arnett (b) (4)	21 Aug 2020 02:23:42

US3732094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:29:56

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Lauren Arnett (b) (4)	21 Aug 2020 02:23:42

US3732094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:29:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	21 Aug 2020 02:23:42

US3732094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:29:56

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '10:35'	Lauren Arnett (b) (4)	21 Aug 2020 02:23:42

US3732094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:29:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered '19 Aug 2020 10:35'	System	21 Aug 2020 02:23:42

US3732094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:29:56

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 02:23:42

US3732094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:29:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'No (N)'	Lauren Arnett (b) (4)	21 Aug 2020 02:23:42

US3732094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:29:56

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Lauren Arnett (b) (4)	21 Aug 2020 02:23:42

US3732094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:29:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered empty.	System	21 Aug 2020 02:23:42

US3732094

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:29:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	21 Aug 2020 02:23:47

US3732094

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:29:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'I'	System	21 Aug 2020 02:23:47

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-19T11:37:24', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'b82d45ca-62c8-4fc5-ba96-1bac730d2962'	System	19 Aug 2020 18:37:52
User entered 'Yes (Y)'	System	19 Aug 2020 18:37:52

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-19T11:37:28', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'b82d45ca-62c8-4fc5-ba96-1bac730d2962' User entered '97.7'	System	19 Aug 2020 18:37:52
	System	19 Aug 2020 18:37:52

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-19T11:37:30', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'b82d45ca-62c8-4fc5-ba96-1bac730d2962'	System	19 Aug 2020 18:37:52
User entered 'No (N)'	System	19 Aug 2020 18:37:52

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-19T11:37:49', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'b82d45ca-62c8-4fc5-ba96-1bac730d2962' User entered '19 Aug 2020 11:37'	System	19 Aug 2020 18:37:52
	System	19 Aug 2020 18:37:52

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '19 Aug 2020 11:22'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '19 Aug 2020 13:52'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-19T14:47:48', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'b94999ce-edbd-4876-b1d0-b88b8c73ebc9' User entered 'Yes (Y)'	System	19 Aug 2020 23:34:34
	System	19 Aug 2020 23:34:34

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-19T16:34:22', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'b94999ce-edbd-4876-b1d0-b88b8c73ebc9' User entered '97.4'	System	19 Aug 2020 23:34:34
	System	19 Aug 2020 23:34:34

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-19T16:34:27', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'b94999ce-edbd-4876-b1d0-b88b8c73ebc9'	System	19 Aug 2020 23:34:34
User entered 'No (N)'	System	19 Aug 2020 23:34:34

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-19T16:34:32', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'b94999ce-edbd-4876-b1d0-b88b8c73ebc9' User entered '19 Aug 2020 16:34'	System	19 Aug 2020 23:34:34
	System	19 Aug 2020 23:34:34

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '19 Aug 2020 14:47'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered 'Day 2'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-20T16:41:11', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '5b7ba69a-a8cd-4b1a-ad2a-64e467d6b79b' User entered 'Yes (Y)'	System	20 Aug 2020 23:41:26
	System	20 Aug 2020 23:41:26

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-20T16:41:15', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '5b7ba69a-a8cd-4b1a-ad2a-64e467d6b79b' User entered '98.1'	System	20 Aug 2020 23:41:26
	System	20 Aug 2020 23:41:26

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-20T16:41:19', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '5b7ba69a-a8cd-4b1a-ad2a-64e467d6b79b' User entered 'No (N)'	System	20 Aug 2020 23:41:26
	System	20 Aug 2020 23:41:26

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-20T16:41:23', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '5b7ba69a-a8cd-4b1a-ad2a-64e467d6b79b' User entered '20 Aug 2020 16:41'	System	20 Aug 2020 23:41:26
	System	20 Aug 2020 23:41:26

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered 'Day 3'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-21T12:00:24', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '93a463e0-a9bf-4ad7-9233-bcb9b7b6b9c5' User entered 'Yes (Y)'	System	21 Aug 2020 19:01:24
	System	21 Aug 2020 19:01:24

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-21T12:01:12', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '93a463e0-a9bf-4ad7-9233-bcb9b7b6b9c5' User entered '98.0'	System	21 Aug 2020 19:01:24
	System	21 Aug 2020 19:01:24

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-21T12:01:15', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '93a463e0-a9bf-4ad7-9233-bcb9b7b6b9c5'	System	21 Aug 2020 19:01:24
User entered 'No (N)'	System	21 Aug 2020 19:01:24

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-21T12:01:18', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '93a463e0-a9bf-4ad7-9233-bcb9b7b6b9c5' User entered '21 Aug 2020 12:01'	System	21 Aug 2020 19:01:24
	System	21 Aug 2020 19:01:24

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered 'Day 4'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-22T21:43:33', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '25edc668-9cd0-4ee4-9c4b-d4cfc7e224fa' User entered 'Yes (Y)'	System	23 Aug 2020 04:43:49
	System	23 Aug 2020 04:43:49

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-22T21:43:37', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '25edc668-9cd0-4ee4-9c4b-d4cfc7e224fa' User entered '98.1'	System	23 Aug 2020 04:43:49
	System	23 Aug 2020 04:43:49

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-22T21:43:40', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '25edc668-9cd0-4ee4-9c4b-d4cfc7e224fa' User entered 'No (N)'	System	23 Aug 2020 04:43:49
	System	23 Aug 2020 04:43:49

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-22T21:43:43', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '25edc668-9cd0-4ee4-9c4b-d4cfc7e224fa' User entered '22 Aug 2020 21:43'	System	23 Aug 2020 04:43:49
	System	23 Aug 2020 04:43:49

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered 'Day 5'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-23T12:00:40', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'f5e76ca0-d3ab-4730-842b-0fb71ee227a6' User entered 'Yes (Y)'	System	23 Aug 2020 19:00:52
	System	23 Aug 2020 19:00:52

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-23T12:00:43', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'f5e76ca0-d3ab-4730-842b-0fb71ee227a6' User entered '98.2'	System	23 Aug 2020 19:00:52
	System	23 Aug 2020 19:00:52

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-23T12:00:45', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'f5e76ca0-d3ab-4730-842b-0fb71ee227a6'	System	23 Aug 2020 19:00:52
User entered 'No (N)'	System	23 Aug 2020 19:00:52

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-23T12:00:48', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'f5e76ca0-d3ab-4730-842b-0fb71ee227a6' User entered '23 Aug 2020 12:00'	System	23 Aug 2020 19:00:52
	System	23 Aug 2020 19:00:52

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered 'Day 6'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-24T13:22:16', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '55b6bf44-7630-453e-a070-ea63b92bdb6d' User entered 'Yes (Y)'	System	24 Aug 2020 20:22:29
	System	24 Aug 2020 20:22:29

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-24T13:22:21', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '55b6bf44-7630-453e-a070-ea63b92bdb6d' User entered '98.0'	System	24 Aug 2020 20:22:29
	System	24 Aug 2020 20:22:29

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-24T13:22:23', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '55b6bf44-7630-453e-a070-ea63b92bdb6d' User entered 'No (N)'	System	24 Aug 2020 20:22:29
	System	24 Aug 2020 20:22:29

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-24T13:22:28', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '55b6bf44-7630-453e-a070-ea63b92bdb6d' User entered '24 Aug 2020 13:22'	System	24 Aug 2020 20:22:29
	System	24 Aug 2020 20:22:29

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered 'Day 7'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-25T15:12:13', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '09ec1247-2023-4a01-b59b-03958b635d3a'	System	25 Aug 2020 22:12:26
User entered 'Yes (Y)'	System	25 Aug 2020 22:12:26

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-25T15:12:17', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '09ec1247-2023-4a01-b59b-03958b635d3a' User entered '97.4'	System	25 Aug 2020 22:12:26
	System	25 Aug 2020 22:12:26

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-25T15:12:20', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '09ec1247-2023-4a01-b59b-03958b635d3a'	System	25 Aug 2020 22:12:26
User entered 'No (N)'	System	25 Aug 2020 22:12:26

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-25T15:12:23', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '09ec1247-2023-4a01-b59b-03958b635d3a'	System	25 Aug 2020 22:12:26
User entered '25 Aug 2020 15:12'	System	25 Aug 2020 22:12:26

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-19T11:38:03', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '69881358-0503-4628-afd2-aab427e19b2a' User entered 'None (1)'	System	19 Aug 2020 19:44:37
	System	19 Aug 2020 19:44:37

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-19T12:44:21', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '69881358-0503-4628-afd2-aab427e19b2a' User entered 'No (N)'	System	19 Aug 2020 19:44:37
	System	19 Aug 2020 19:44:37

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-19T12:44:23', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '69881358-0503-4628-afd2-aab427e19b2a' User entered 'No (N)'	System	19 Aug 2020 19:44:37
	System	19 Aug 2020 19:44:37

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-19T12:44:27', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '69881358-0503-4628-afd2-aab427e19b2a' User entered 'None (1)'	System	19 Aug 2020 19:44:37
	System	19 Aug 2020 19:44:37

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-19T12:44:35', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '69881358-0503-4628-afd2-aab427e19b2a' User entered '19 Aug 2020 12:44'	System	19 Aug 2020 19:44:37
	System	19 Aug 2020 19:44:37

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '19 Aug 2020 11:22'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '19 Aug 2020 13:52'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-19T16:34:37', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '56abf285-3208-4440-9a37-5606cc52c7d1'	System	19 Aug 2020 23:34:57
User entered 'None (1)'	System	19 Aug 2020 23:34:57

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-19T16:34:39', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '56abf285-3208-4440-9a37-5606cc52c7d1' User entered 'No (N)'	System	19 Aug 2020 23:34:57
	System	19 Aug 2020 23:34:57

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-19T16:34:47', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '56abf285-3208-4440-9a37-5606cc52c7d1' User entered 'No (N)'	System	19 Aug 2020 23:34:57
	System	19 Aug 2020 23:34:57

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-19T16:34:51', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '56abf285-3208-4440-9a37-5606cc52c7d1'	System	19 Aug 2020 23:34:57
User entered 'None (1)'	System	19 Aug 2020 23:34:57

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-19T16:34:54', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '56abf285-3208-4440-9a37-5606cc52c7d1' User entered '19 Aug 2020 16:34'	System	19 Aug 2020 23:34:57
	System	19 Aug 2020 23:34:57

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '19 Aug 2020 14:47'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered 'Day 2'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-20T16:41:34', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'f4f15663-a4ae-4293-b7d4-713a243e1194'	System	20 Aug 2020 23:41:49
User entered 'Does not interfere with activity (2)'	System	20 Aug 2020 23:41:49

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-20T16:41:37', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'f4f15663-a4ae-4293-b7d4-713a243e1194'	System	20 Aug 2020 23:41:49
User entered 'No (N)'	System	20 Aug 2020 23:41:49

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-20T16:41:40', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'f4f15663-a4ae-4293-b7d4-713a243e1194'	System	20 Aug 2020 23:41:49
User entered 'No (N)'	System	20 Aug 2020 23:41:49

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-20T16:41:43', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'f4f15663-a4ae-4293-b7d4-713a243e1194'	System	20 Aug 2020 23:41:49
User entered 'None (1)'	System	20 Aug 2020 23:41:49

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-20T16:41:47', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'f4f15663-a4ae-4293-b7d4-713a243e1194' User entered '20 Aug 2020 16:41'	System	20 Aug 2020 23:41:49
	System	20 Aug 2020 23:41:49

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered 'Day 3'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-21T12:01:23', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'c0919b62-61d2-490a-88bd-ef2fed01bf74'	System	21 Aug 2020 19:01:41
User entered 'Does not interfere with activity (2)'	System	21 Aug 2020 19:01:41

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-21T12:01:25', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'c0919b62-61d2-490a-88bd-ef2fed01bf74'	System	21 Aug 2020 19:01:41
User entered 'No (N)'	System	21 Aug 2020 19:01:41

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-21T12:01:27', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'c0919b62-61d2-490a-88bd-ef2fed01bf74'	System	21 Aug 2020 19:01:41
User entered 'No (N)'	System	21 Aug 2020 19:01:41

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-21T12:01:29', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'c0919b62-61d2-490a-88bd-ef2fed01bf74'	System	21 Aug 2020 19:01:41
User entered 'None (1)'	System	21 Aug 2020 19:01:41

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-21T12:01:33', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'c0919b62-61d2-490a-88bd-ef2fed01bf74' User entered '21 Aug 2020 12:01'	System	21 Aug 2020 19:01:41
	System	21 Aug 2020 19:01:41

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered 'Day 4'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-22T21:43:48', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '6d2eab52-3b47-41ea-8e07-c045cb17f615'	System	23 Aug 2020 04:43:59
User entered 'None (1)'	System	23 Aug 2020 04:43:59

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-22T21:43:50', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '6d2eab52-3b47-41ea-8e07-c045cb17f615' User entered 'No (N)'	System	23 Aug 2020 04:43:59
	System	23 Aug 2020 04:43:59

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-22T21:43:52', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '6d2eab52-3b47-41ea-8e07-c045cb17f615' User entered 'No (N)'	System	23 Aug 2020 04:43:59
	System	23 Aug 2020 04:43:59

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-22T21:43:56', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '6d2eab52-3b47-41ea-8e07-c045cb17f615'	System	23 Aug 2020 04:43:59
User entered 'None (1)'	System	23 Aug 2020 04:43:59

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-22T21:43:58', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '6d2eab52-3b47-41ea-8e07-c045cb17f615' User entered '22 Aug 2020 21:43'	System	23 Aug 2020 04:43:59
	System	23 Aug 2020 04:43:59

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered 'Day 5'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-23T12:00:52', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '83aa2135-21d1-4691-859f-263989417dd0'	System	23 Aug 2020 19:01:07
User entered 'None (1)'	System	23 Aug 2020 19:01:07

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-23T12:00:54', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '83aa2135-21d1-4691-859f-263989417dd0'	System	23 Aug 2020 19:01:07
User entered 'No (N)'	System	23 Aug 2020 19:01:07

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-23T12:00:56', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '83aa2135-21d1-4691-859f-263989417dd0'	System	23 Aug 2020 19:01:07
User entered 'No (N)'	System	23 Aug 2020 19:01:07

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-23T12:00:59', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '83aa2135-21d1-4691-859f-263989417dd0'	System	23 Aug 2020 19:01:07
User entered 'None (1)'	System	23 Aug 2020 19:01:07

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-23T12:01:02', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '83aa2135-21d1-4691-859f-263989417dd0' User entered '23 Aug 2020 12:01'	System	23 Aug 2020 19:01:07
	System	23 Aug 2020 19:01:07

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered 'Day 6'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-24T13:22:37', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '2e8875d3-3f55-4ecd-9a92-f1c427f66717'	System	24 Aug 2020 20:22:55
User entered 'None (1)'	System	24 Aug 2020 20:22:55

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-24T13:22:39', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '2e8875d3-3f55-4ecd-9a92-f1c427f66717'	System	24 Aug 2020 20:22:55
User entered 'No (N)'	System	24 Aug 2020 20:22:55

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-24T13:22:44', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '2e8875d3-3f55-4ecd-9a92-f1c427f66717'	System	24 Aug 2020 20:22:55
User entered 'No (N)'	System	24 Aug 2020 20:22:55

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-24T13:22:49', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '2e8875d3-3f55-4ecd-9a92-f1c427f66717'	System	24 Aug 2020 20:22:55
User entered 'None (1)'	System	24 Aug 2020 20:22:55

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-24T13:22:52', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '2e8875d3-3f55-4ecd-9a92-f1c427f66717'	System	24 Aug 2020 20:22:55
User entered '24 Aug 2020 13:22'	System	24 Aug 2020 20:22:55

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered 'Day 7'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-25T15:12:27', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '22504fb2-0325-42c1-a11f-28c29678f7d5'	System	25 Aug 2020 22:12:36
User entered 'None (1)'	System	25 Aug 2020 22:12:36

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-25T15:12:29', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '22504fb2-0325-42c1-a11f-28c29678f7d5'	System	25 Aug 2020 22:12:36
User entered 'No (N)'	System	25 Aug 2020 22:12:36

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-25T15:12:30', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '22504fb2-0325-42c1-a11f-28c29678f7d5'	System	25 Aug 2020 22:12:36
User entered 'No (N)'	System	25 Aug 2020 22:12:36

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-25T15:12:32', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '22504fb2-0325-42c1-a11f-28c29678f7d5' User entered 'None (1)'	System	25 Aug 2020 22:12:36
	System	25 Aug 2020 22:12:36

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-25T15:12:34', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '22504fb2-0325-42c1-a11f-28c29678f7d5' User entered '25 Aug 2020 15:12'	System	25 Aug 2020 22:12:36
	System	25 Aug 2020 22:12:36

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-19T12:44:41', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '3f31f158-75ea-47f1-b027-0f43a5a204a6' User entered 'None (0)'	System	19 Aug 2020 19:45:07
	System	19 Aug 2020 19:45:07

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-19T12:44:43', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '3f31f158-75ea-47f1-b027-0f43a5a204a6' User entered 'None (0)'	System	19 Aug 2020 19:45:07
	System	19 Aug 2020 19:45:07

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-19T12:44:45', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '3f31f158-75ea-47f1-b027-0f43a5a204a6' User entered 'None (0)'	System	19 Aug 2020 19:45:07
	System	19 Aug 2020 19:45:07

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-19T12:44:49', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '3f31f158-75ea-47f1-b027-0f43a5a204a6' User entered 'None (0)'	System	19 Aug 2020 19:45:07
	System	19 Aug 2020 19:45:07

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-19T12:44:51', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '3f31f158-75ea-47f1-b027-0f43a5a204a6' User entered 'None (0)'	System	19 Aug 2020 19:45:07
	System	19 Aug 2020 19:45:07

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-19T12:44:52', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '3f31f158-75ea-47f1-b027-0f43a5a204a6' User entered 'None (0)'	System	19 Aug 2020 19:45:07
	System	19 Aug 2020 19:45:07

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

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)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-19T12:44:59', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '3f31f158-75ea-47f1-b027-0f43a5a204a6' User entered 'No (N)'	System	19 Aug 2020 19:45:07
	System	19 Aug 2020 19:45:07

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-19T12:45:04', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '3f31f158-75ea-47f1-b027-0f43a5a204a6' User entered '19 Aug 2020 12:45'	System	19 Aug 2020 19:45:07
	System	19 Aug 2020 19:45:07

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '19 Aug 2020 11:22'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '19 Aug 2020 13:52'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-19T16:34:59', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'd477e6e2-43e2-4ef0-bc4c-abc797d54a3c' User entered 'None (0)'	System	19 Aug 2020 23:35:31
	System	19 Aug 2020 23:35:31

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-19T16:35:16', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'd477e6e2-43e2-4ef0-bc4c-abc797d54a3c'	System	19 Aug 2020 23:35:31
User entered 'No interference with activity (1)'	System	19 Aug 2020 23:35:31

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-19T16:35:10', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'd477e6e2-43e2-4ef0-bc4c-abc797d54a3c' User entered 'None (0)'	System	19 Aug 2020 23:35:31
	System	19 Aug 2020 23:35:31

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-19T16:35:19', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'd477e6e2-43e2-4ef0-bc4c-abc797d54a3c' User entered 'None (0)'	System	19 Aug 2020 23:35:31
	System	19 Aug 2020 23:35:31

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-19T16:35:20', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'd477e6e2-43e2-4ef0-bc4c-abc797d54a3c' User entered 'None (0)'	System	19 Aug 2020 23:35:31
	System	19 Aug 2020 23:35:31

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-19T16:35:22', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'd477e6e2-43e2-4ef0-bc4c-abc797d54a3c' User entered 'None (0)'	System	19 Aug 2020 23:35:31
	System	19 Aug 2020 23:35:31

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

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)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-19T16:35:26', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'd477e6e2-43e2-4ef0-bc4c-abc797d54a3c' User entered 'No (N)'	System	19 Aug 2020 23:35:31
	System	19 Aug 2020 23:35:31

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-19T16:35:28', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'd477e6e2-43e2-4ef0-bc4c-abc797d54a3c'	System	19 Aug 2020 23:35:31
User entered '19 Aug 2020 16:35'	System	19 Aug 2020 23:35:31

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '19 Aug 2020 14:47'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered 'Day 2'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-20T16:41:55', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '871343e1-0364-4de7-adb6-4905978d1d70' User entered 'None (0)'	System	20 Aug 2020 23:42:16
	System	20 Aug 2020 23:42:16

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-20T16:42:00', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '871343e1-0364-4de7-adb6-4905978d1d70' User entered 'None (0)'	System	20 Aug 2020 23:42:16
	System	20 Aug 2020 23:42:16

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-20T16:42:02', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '871343e1-0364-4de7-adb6-4905978d1d70' User entered 'None (0)'	System	20 Aug 2020 23:42:16
	System	20 Aug 2020 23:42:16

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-20T16:42:04', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '871343e1-0364-4de7-adb6-4905978d1d70' User entered 'None (0)'	System	20 Aug 2020 23:42:16
	System	20 Aug 2020 23:42:16

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-20T16:42:06', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '871343e1-0364-4de7-adb6-4905978d1d70' User entered 'None (0)'	System	20 Aug 2020 23:42:16
	System	20 Aug 2020 23:42:16

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-20T16:42:08', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '871343e1-0364-4de7-adb6-4905978d1d70'	System	20 Aug 2020 23:42:16
User entered 'None (0)'	System	20 Aug 2020 23:42:16

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:56

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)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-20T16:42:11', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '871343e1-0364-4de7-adb6-4905978d1d70'	System	20 Aug 2020 23:42:16
User entered 'No (N)'	System	20 Aug 2020 23:42:16

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-20T16:42:14', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '871343e1-0364-4de7-adb6-4905978d1d70' User entered '20 Aug 2020 16:42'	System	20 Aug 2020 23:42:16
	System	20 Aug 2020 23:42:16

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered 'Day 3'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-21T12:01:37', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'f9c82a59-774d-4278-bcdb-0ab7f1d607ee' User entered 'None (0)'	System	21 Aug 2020 19:01:57
	System	21 Aug 2020 19:01:57

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-21T12:01:42', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'f9c82a59-774d-4278-bcdb-0ab7f1d607ee' User entered 'None (0)'	System	21 Aug 2020 19:01:57
	System	21 Aug 2020 19:01:57

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-21T12:01:44', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'f9c82a59-774d-4278-bcdb-0ab7f1d607ee' User entered 'None (0)'	System	21 Aug 2020 19:01:57
	System	21 Aug 2020 19:01:57

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-21T12:01:45', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'f9c82a59-774d-4278-bcdb-0ab7f1d607ee' User entered 'None (0)'	System	21 Aug 2020 19:01:57
	System	21 Aug 2020 19:01:57

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-21T12:01:47', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'f9c82a59-774d-4278-bcdb-0ab7f1d607ee' User entered 'None (0)'	System	21 Aug 2020 19:01:57
	System	21 Aug 2020 19:01:57

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-21T12:01:49', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'f9c82a59-774d-4278-bcdb-0ab7f1d607ee' User entered 'None (0)'	System	21 Aug 2020 19:01:57
	System	21 Aug 2020 19:01:57

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:56

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)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-21T12:01:52', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'f9c82a59-774d-4278-bcdb-0ab7f1d607ee' User entered 'No (N)'	System	21 Aug 2020 19:01:57
	System	21 Aug 2020 19:01:57

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-21T12:01:54', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'f9c82a59-774d-4278-bcdb-0ab7f1d607ee' User entered '21 Aug 2020 12:01'	System	21 Aug 2020 19:01:57
	System	21 Aug 2020 19:01:57

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered 'Day 4'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-22T21:44:02', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'f933e6c7-7d6a-46bb-afe6-ee2d517d5ff9' User entered 'None (0)'	System	23 Aug 2020 04:44:21
	System	23 Aug 2020 04:44:21

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-22T21:44:04', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'f933e6c7-7d6a-46bb-afe6-ee2d517d5ff9' User entered 'None (0)'	System	23 Aug 2020 04:44:21
	System	23 Aug 2020 04:44:21

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-22T21:44:06', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'f933e6c7-7d6a-46bb-afe6-ee2d517d5ff9' User entered 'None (0)'	System	23 Aug 2020 04:44:21
	System	23 Aug 2020 04:44:21

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-22T21:44:07', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'f933e6c7-7d6a-46bb-afe6-ee2d517d5ff9'	System	23 Aug 2020 04:44:21
User entered 'None (0)'	System	23 Aug 2020 04:44:21

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-22T21:44:09', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'f933e6c7-7d6a-46bb-afe6-ee2d517d5ff9' User entered 'None (0)'	System	23 Aug 2020 04:44:21
	System	23 Aug 2020 04:44:21

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-22T21:44:11', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'f933e6c7-7d6a-46bb-afe6-ee2d517d5ff9'	System	23 Aug 2020 04:44:21
User entered 'None (0)'	System	23 Aug 2020 04:44:21

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:56

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)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-22T21:44:15', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'f933e6c7-7d6a-46bb-afe6-ee2d517d5ff9'	System	23 Aug 2020 04:44:21
User entered 'No (N)'	System	23 Aug 2020 04:44:21

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-22T21:44:18', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'f933e6c7-7d6a-46bb-afe6-ee2d517d5ff9' User entered '22 Aug 2020 21:44'	System	23 Aug 2020 04:44:21
	System	23 Aug 2020 04:44:21

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered 'Day 5'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-23T12:01:06', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '56f71853-0851-44aa-9a0e-339e42bb4c9e' User entered 'None (0)'	System	23 Aug 2020 19:01:23
	System	23 Aug 2020 19:01:23

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-23T12:01:08', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '56f71853-0851-44aa-9a0e-339e42bb4c9e' User entered 'None (0)'	System	23 Aug 2020 19:01:23
	System	23 Aug 2020 19:01:23

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-23T12:01:09', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '56f71853-0851-44aa-9a0e-339e42bb4c9e' User entered 'None (0)'	System	23 Aug 2020 19:01:23
	System	23 Aug 2020 19:01:23

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-23T12:01:11', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '56f71853-0851-44aa-9a0e-339e42bb4c9e' User entered 'None (0)'	System	23 Aug 2020 19:01:23
	System	23 Aug 2020 19:01:23

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-23T12:01:13', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '56f71853-0851-44aa-9a0e-339e42bb4c9e' User entered 'None (0)'	System	23 Aug 2020 19:01:23
	System	23 Aug 2020 19:01:23

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-23T12:01:14', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '56f71853-0851-44aa-9a0e-339e42bb4c9e' User entered 'None (0)'	System	23 Aug 2020 19:01:23
	System	23 Aug 2020 19:01:23

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:56

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)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-23T12:01:17', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '56f71853-0851-44aa-9a0e-339e42bb4c9e' User entered 'No (N)'	System	23 Aug 2020 19:01:23
	System	23 Aug 2020 19:01:23

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-23T12:01:19', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '56f71853-0851-44aa-9a0e-339e42bb4c9e' User entered '23 Aug 2020 12:01'	System	23 Aug 2020 19:01:23
	System	23 Aug 2020 19:01:23

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered 'Day 6'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-24T13:22:55', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '0a5bb7cb-9777-408b-ba84-61a8ad5e648f' User entered 'None (0)'	System	24 Aug 2020 20:23:18
	System	24 Aug 2020 20:23:18

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-24T13:23:10', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '0a5bb7cb-9777-408b-ba84-61a8ad5e648f' User entered 'No interference with activity (1)'	System	24 Aug 2020 20:23:18
	System	24 Aug 2020 20:23:18

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-24T13:23:06', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '0a5bb7cb-9777-408b-ba84-61a8ad5e648f' User entered 'None (0)'	System	24 Aug 2020 20:23:18
	System	24 Aug 2020 20:23:18

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-24T13:23:05', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '0a5bb7cb-9777-408b-ba84-61a8ad5e648f' User entered 'None (0)'	System	24 Aug 2020 20:23:18
	System	24 Aug 2020 20:23:18

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-24T13:23:04', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '0a5bb7cb-9777-408b-ba84-61a8ad5e648f' User entered 'None (0)'	System	24 Aug 2020 20:23:18
	System	24 Aug 2020 20:23:18

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-24T13:23:13', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '0a5bb7cb-9777-408b-ba84-61a8ad5e648f' User entered 'None (0)'	System	24 Aug 2020 20:23:18
	System	24 Aug 2020 20:23:18

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:56

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)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-24T13:23:14', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '0a5bb7cb-9777-408b-ba84-61a8ad5e648f' User entered 'No (N)'	System	24 Aug 2020 20:23:18
	System	24 Aug 2020 20:23:18

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-24T13:23:17', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '0a5bb7cb-9777-408b-ba84-61a8ad5e648f' User entered '24 Aug 2020 13:23'	System	24 Aug 2020 20:23:18
	System	24 Aug 2020 20:23:18

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered 'Day 7'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-25T15:12:38', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '831b5547-3a25-4a93-bc00-026ac0fa70be' User entered 'None (0)'	System	25 Aug 2020 22:12:55
	System	25 Aug 2020 22:12:55

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-25T15:12:40', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '831b5547-3a25-4a93-bc00-026ac0fa70be'	System	25 Aug 2020 22:12:55
User entered 'No interference with activity (1)'	System	25 Aug 2020 22:12:55

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-25T15:12:42', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '831b5547-3a25-4a93-bc00-026ac0fa70be' User entered 'None (0)'	System	25 Aug 2020 22:12:55
	System	25 Aug 2020 22:12:55

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-25T15:12:43', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '831b5547-3a25-4a93-bc00-026ac0fa70be' User entered 'None (0)'	System	25 Aug 2020 22:12:55
	System	25 Aug 2020 22:12:55

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-25T15:12:44', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '831b5547-3a25-4a93-bc00-026ac0fa70be' User entered 'None (0)'	System	25 Aug 2020 22:12:55
	System	25 Aug 2020 22:12:55

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-25T15:12:45', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '831b5547-3a25-4a93-bc00-026ac0fa70be' User entered 'None (0)'	System	25 Aug 2020 22:12:55
	System	25 Aug 2020 22:12:55

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:56

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)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-25T15:12:48', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '831b5547-3a25-4a93-bc00-026ac0fa70be' User entered 'No (N)'	System	25 Aug 2020 22:12:55
	System	25 Aug 2020 22:12:55

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-25T15:12:51', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '831b5547-3a25-4a93-bc00-026ac0fa70be' User entered '25 Aug 2020 15:12'	System	25 Aug 2020 22:12:55
	System	25 Aug 2020 22:12:55

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 18:05:17

US3732094

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	24 Aug 2020 20:23:18
User entered 'Day 8'	System	24 Aug 2020 20:23:18

US3732094

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:29:56

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-27T05:59:41', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '6459a465-055e-4ec5-8116-580bea047a2c' User entered 'None (0)'	System	27 Aug 2020 12:59:52
	System	27 Aug 2020 12:59:52

US3732094

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:29:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-27T05:59:46', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '6459a465-055e-4ec5-8116-580bea047a2c' User entered '27 Aug 2020 05:59'	System	27 Aug 2020 12:59:52
	System	27 Aug 2020 12:59:52

US3732094

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 20:23:18

US3732094

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 20:23:18

US3732094

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	24 Aug 2020 20:23:18
User entered 'Day 8'	System	24 Aug 2020 20:23:18

US3732094

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:29:56

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)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-27T05:59:52', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'e0f35e7c-fede-4b63-bfed-960e8d122ebf' User entered 'No (N)'	System	27 Aug 2020 12:59:58
	System	27 Aug 2020 12:59:58

US3732094

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:29:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-08-27T05:59:55', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'e0f35e7c-fede-4b63-bfed-960e8d122ebf' User entered '27 Aug 2020 05:59'	System	27 Aug 2020 12:59:58
	System	27 Aug 2020 12:59:58

US3732094

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 20:23:18

US3732094

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 20:23:18

US3732094

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	27 Aug 2020 16:39:23

US3732094

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '26 Aug 2020'	Lauren Arnett (b) (4)	27 Aug 2020 16:39:23

US3732094

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Contact Made (CONTACT MADE)'	Lauren Arnett (b) (4)	27 Aug 2020 16:39:23

US3732094

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Lauren Arnett (b) (4)	27 Aug 2020 16:39:23

US3732094

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	27 Aug 2020 16:39:36

US3732094

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'I'	System	27 Aug 2020 16:39:36

US3732094

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Linda Vega (b) (4)	02 Sep 2020 21:58:43

US3732094

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '02 Sep 2020'	Linda Vega (b) (4)	02 Sep 2020 21:58:43

US3732094

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4)	02 Sep 2020 21:58:43

US3732094

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Linda Vega (b) (4)	02 Sep 2020 21:58:43

US3732094

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Linda Vega (b) (4)	02 Sep 2020 21:58:48

US3732094

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'I'	System	02 Sep 2020 21:58:48

US3732094

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Linda Vega (b) (4)	09 Sep 2020 20:25:08

US3732094

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '09 Sep 2020'	Linda Vega (b) (4)	09 Sep 2020 20:25:08

US3732094

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4)	09 Sep 2020 20:25:08

US3732094

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Linda Vega (b) (4)	09 Sep 2020 20:25:08

US3732094

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Linda Vega (b) (4)	09 Sep 2020 20:25:13

US3732094

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'I'	System	09 Sep 2020 20:25:13

US3732094

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	18 Sep 2020 21:18:50

US3732094

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:56

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '16 Sep 2020'	Lauren Arnett (b) (4)	18 Sep 2020 21:18:50

US3732094

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:56

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Clinic (Clinic)'	Lauren Arnett (b) (4)	18 Sep 2020 21:18:50

US3732094

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'VISIT2'	System	18 Sep 2020 21:18:50

US3732094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User accepted default value 'Pre-Dose (PREDOSE)'	Lauren Arnett (b) (4)	18 Sep 2020 21:20:22
	(b) (4)	

US3732094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	18 Sep 2020 21:20:22

US3732094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '16 Sep 2020'	Lauren Arnett (b) (4)	18 Sep 2020 21:20:22

US3732094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '09:05'	Lauren Arnett (b) (4)	18 Sep 2020 21:20:22

US3732094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered '16 Sep 2020 09:05'	System	18 Sep 2020 21:20:22

US3732094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '98.0' F	Lauren Arnett (b) (4)	18 Sep 2020 21:20:22

US3732094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Oral (Oral)'	Lauren Arnett (b) (4)	18 Sep 2020 21:20:22

US3732094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Lauren Arnett (b) (4)	18 Sep 2020 21:20:22

US3732094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '70'	Lauren Arnett (b) (4)	18 Sep 2020 21:20:22

US3732094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'bpm'	System	18 Sep 2020 21:20:22

US3732094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '16'	Lauren Arnett (b) (4)	18 Sep 2020 21:20:22

US3732094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'breaths/min'	System	18 Sep 2020 21:20:22

US3732094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:56

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '149'	Lauren Arnett (b) (4)	18 Sep 2020 21:20:22

US3732094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'mmHg'	System	18 Sep 2020 21:20:22

US3732094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:56

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '92'	Lauren Arnett (b) (4)	18 Sep 2020 21:20:22

US3732094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'mmHg'	System	18 Sep 2020 21:20:22

US3732094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User accepted default value 'Post-Dose (POSTDOSE)'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 21:20:22

US3732094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	18 Sep 2020 21:20:22

US3732094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '16 Sep 2020'	Lauren Arnett (b) (4)	18 Sep 2020 21:20:22

US3732094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '10:25'	Lauren Arnett (b) (4)	18 Sep 2020 21:20:22

US3732094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered '16 Sep 2020 10:25'	System	18 Sep 2020 21:20:22

US3732094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '98.3' F	Lauren Arnett (b) (4)	18 Sep 2020 21:20:22

US3732094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Oral (Oral)'	Lauren Arnett (b) (4)	18 Sep 2020 21:20:22

US3732094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Lauren Arnett (b) (4)	18 Sep 2020 21:20:22

US3732094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '67'	Lauren Arnett (b) (4)	18 Sep 2020 21:20:22

US3732094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'bpm'	System	18 Sep 2020 21:20:22

US3732094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '16'	Lauren Arnett (b) (4)	18 Sep 2020 21:20:22

US3732094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'breaths/min'	System	18 Sep 2020 21:20:22

US3732094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '142'	Lauren Arnett (b) (4)	18 Sep 2020 21:20:22

US3732094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'mmHg'	System	18 Sep 2020 21:20:22

US3732094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:56

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '95'	Lauren Arnett (b) (4)	18 Sep 2020 21:20:22

US3732094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'mmHg'	System	18 Sep 2020 21:20:22

US3732094

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	18 Sep 2020 21:20:41

US3732094

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '16 Sep 2020'	Lauren Arnett (b) (4)	18 Sep 2020 21:20:41

US3732094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:56

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	16 Sep 2020 16:58:49

US3732094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:56

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Lauren Arnett (b) (4)	16 Sep 2020 16:58:49

US3732094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:56

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 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Lauren Arnett (b) (4)	16 Sep 2020 16:58:49

US3732094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:56

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 16:58:49

US3732094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:56

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '16 Sep 2020'	Lauren Arnett (b) (4)	16 Sep 2020 16:58:49

US3732094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:56

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '09:55'	Lauren Arnett (b) (4)	16 Sep 2020 16:58:49

US3732094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:56

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered '16 Sep 2020 09:55'	System	16 Sep 2020 16:58:49

US3732094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:56

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Left Arm (LEFT ARM)'	Lauren Arnett (b) (4)	16 Sep 2020 16:58:49

US3732094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:56

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'ONCE'	System	16 Sep 2020 16:58:49

US3732094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:56

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 16:58:49

US3732094

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	18 Sep 2020 21:21:01

US3732094

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:56

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '16 Sep 2020'	Lauren Arnett (b) (4)	18 Sep 2020 21:21:01

US3732094

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:56

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '09:27'	Lauren Arnett (b) (4)	18 Sep 2020 21:21:01

US3732094

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered '16 Sep 2020 09:27'	System	18 Sep 2020 21:21:01

US3732094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:29:56

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '16 Sep 2020'	Lauren Arnett (b) (4)	18 Sep 2020 21:21:14

US3732094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:29:56

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 21:21:14

US3732094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:29:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	18 Sep 2020 21:21:14

US3732094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:29:56

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '09:18'	Lauren Arnett (b) (4)	18 Sep 2020 21:21:14

US3732094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:29:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered '16 Sep 2020 09:18'	System	18 Sep 2020 21:21:14

US3732094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:29:56

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 21:21:14

US3732094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:29:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'No (N)'	Lauren Arnett (b) (4)	18 Sep 2020 21:21:14

US3732094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:29:56

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Lauren Arnett (b) (4)	18 Sep 2020 21:21:14

US3732094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:29:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered empty.	System	18 Sep 2020 21:21:14

US3732094

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	18 Sep 2020 21:21:22

US3732094

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'I'	System	18 Sep 2020 21:21:22

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	16 Sep 2020 16:58:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-16T11:33:07', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'b342ec76-18e4-4509-a20c-30ce62c534da' User entered 'Yes (Y)'	System	16 Sep 2020 18:33:21
	System	16 Sep 2020 18:33:21

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-16T11:33:10', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'b342ec76-18e4-4509-a20c-30ce62c534da' User entered '98.3'	System	16 Sep 2020 18:33:21
	System	16 Sep 2020 18:33:21

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-16T11:33:13', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'b342ec76-18e4-4509-a20c-30ce62c534da' User entered 'No (N)'	System	16 Sep 2020 18:33:21
	System	16 Sep 2020 18:33:21

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-16T11:33:19', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'b342ec76-18e4-4509-a20c-30ce62c534da' User entered '16 Sep 2020 11:33'	System	16 Sep 2020 18:33:21
	System	16 Sep 2020 18:33:21

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '16 Sep 2020 10:15'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '16 Sep 2020 12:45'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	16 Sep 2020 16:58:49
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-16T18:26:23', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'a58dd003-e784-46d8-b1e1-bb6e0e03d4ab' User entered 'Yes (Y)'	System	17 Sep 2020 01:26:36
	System	17 Sep 2020 01:26:36

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-16T18:26:27', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'a58dd003-e784-46d8-b1e1-bb6e0e03d4ab' User entered '98.0'	System	17 Sep 2020 01:26:36
	System	17 Sep 2020 01:26:36

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-16T18:26:31', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'a58dd003-e784-46d8-b1e1-bb6e0e03d4ab'	System	17 Sep 2020 01:26:36
User entered 'No (N)'	System	17 Sep 2020 01:26:36

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-16T18:26:34', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'a58dd003-e784-46d8-b1e1-bb6e0e03d4ab' User entered '16 Sep 2020 18:26'	System	17 Sep 2020 01:26:36
	System	17 Sep 2020 01:26:36

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '16 Sep 2020 13:40'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	16 Sep 2020 16:58:49
User entered 'Day 2'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-17T16:03:14', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'b7e35988-a7f4-4329-bfa3-bdce20b53c00' User entered 'Yes (Y)'	System	17 Sep 2020 23:03:37
	System	17 Sep 2020 23:03:37

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-17T16:03:18', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'b7e35988-a7f4-4329-bfa3-bdce20b53c00' User entered '100.2'	System	17 Sep 2020 23:03:37
	System	17 Sep 2020 23:03:37

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-17T16:03:24', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'b7e35988-a7f4-4329-bfa3-bdce20b53c00'	System	17 Sep 2020 23:03:37
User entered 'Yes (Y)'	System	17 Sep 2020 23:03:37

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:56

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'con meds updated, please note medication was taken for past medical history' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 19:32:23
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-17T16:03:28', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'b7e35988-a7f4-4329-bfa3-bdce20b53c00'	Lauren Arnett (b) (4) (b) (4)	25 Sep 2020 16:43:31
User entered '1'	System	17 Sep 2020 23:03:37

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:56

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-17T16:03:28', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'b7e35988-a7f4-4329-bfa3-bdce20b53c00' User entered '0'	System	17 Sep 2020 23:03:37
	System	17 Sep 2020 23:03:37

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-17T16:03:32', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'b7e35988-a7f4-4329-bfa3-bdce20b53c00' User entered '17 Sep 2020 16:03'	System	17 Sep 2020 23:03:37
	System	17 Sep 2020 23:03:37

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	16 Sep 2020 16:58:49
User entered 'Day 3'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:56

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-18T12:14:44', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '84fd42eb-0bcb-442c-8753-6f8e89e9225b' User entered 'Yes (Y)'	System	18 Sep 2020 19:15:35
	System	18 Sep 2020 19:15:35

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-18T12:14:48', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '84fd42eb-0bcb-442c-8753-6f8e89e9225b' User entered '98.2'	System	18 Sep 2020 19:15:35
	System	18 Sep 2020 19:15:35

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-18T12:14:58', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '84fd42eb-0bcb-442c-8753-6f8e89e9225b' User entered 'No (N)'	System	18 Sep 2020 19:15:35
	System	18 Sep 2020 19:15:35

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-18T12:15:29', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '84fd42eb-0bcb-442c-8753-6f8e89e9225b' User entered '18 Sep 2020 12:15'	System	18 Sep 2020 19:15:35
	System	18 Sep 2020 19:15:35

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	16 Sep 2020 16:58:49
User entered 'Day 4'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-19T18:02:45', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '61fb2750-e22d-4b3f-a4d8-183347b2e08c' User entered 'No (N)'	System	20 Sep 2020 01:02:57
	System	20 Sep 2020 01:02:57

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-19T18:02:50', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '61fb2750-e22d-4b3f-a4d8-183347b2e08c' User entered 'No (N)'	System	20 Sep 2020 01:02:57
	System	20 Sep 2020 01:02:57

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-19T18:02:53', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '61fb2750-e22d-4b3f-a4d8-183347b2e08c' User entered '19 Sep 2020 18:02'	System	20 Sep 2020 01:02:57
	System	20 Sep 2020 01:02:57

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	16 Sep 2020 16:58:49
User entered 'Day 5'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:56

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-20T12:01:19', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '0d9c2735-c57c-45cf-98ca-6969f9b201b2' User entered 'Yes (Y)'	System	20 Sep 2020 19:01:36
	System	20 Sep 2020 19:01:36

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-20T12:01:22', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '0d9c2735-c57c-45cf-98ca-6969f9b201b2' User entered '98.2'	System	20 Sep 2020 19:01:36
	System	20 Sep 2020 19:01:36

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-20T12:01:26', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '0d9c2735-c57c-45cf-98ca-6969f9b201b2'	System	20 Sep 2020 19:01:36
User entered 'No (N)'	System	20 Sep 2020 19:01:36

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-20T12:01:33', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '0d9c2735-c57c-45cf-98ca-6969f9b201b2' User entered '20 Sep 2020 12:01'	System	20 Sep 2020 19:01:36
	System	20 Sep 2020 19:01:36

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	16 Sep 2020 16:58:49
User entered 'Day 6'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-21T17:18:50', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'dd9b306b-59c9-44ba-be30-784f7f5bcce2' User entered 'No (N)'	System	22 Sep 2020 00:19:00
	System	22 Sep 2020 00:19:00

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-21T17:18:52', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'dd9b306b-59c9-44ba-be30-784f7f5bcce2'	System	22 Sep 2020 00:19:00
User entered 'No (N)'	System	22 Sep 2020 00:19:00

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-21T17:18:55', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'dd9b306b-59c9-44ba-be30-784f7f5bcce2'	System	22 Sep 2020 00:19:00
User entered '21 Sep 2020 17:18'	System	22 Sep 2020 00:19:00

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	16 Sep 2020 16:58:49
User entered 'Day 7'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:56

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-22T12:00:16', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '732da8b6-476f-4b1d-b32e-5ea1cee1afee' User entered 'No (N)'	System	22 Sep 2020 19:00:23
	System	22 Sep 2020 19:00:23

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-22T12:00:18', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '732da8b6-476f-4b1d-b32e-5ea1cee1afee'	System	22 Sep 2020 19:00:23
User entered 'No (N)'	System	22 Sep 2020 19:00:23

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-22T12:00:21', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '732da8b6-476f-4b1d-b32e-5ea1cee1afee' User entered '22 Sep 2020 12:00'	System	22 Sep 2020 19:00:23
	System	22 Sep 2020 19:00:23

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	16 Sep 2020 16:58:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-16T11:33:25', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'ff3ded3c-b0d2-4f9c-b6af-7ace053b4c8d' User entered 'None (1)'	System	16 Sep 2020 18:33:40
	System	16 Sep 2020 18:33:40

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-16T11:33:28', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'ff3ded3c-b0d2-4f9c-b6af-7ace053b4c8d' User entered 'No (N)'	System	16 Sep 2020 18:33:40
	System	16 Sep 2020 18:33:40

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-16T11:33:30', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'ff3ded3c-b0d2-4f9c-b6af-7ace053b4c8d' User entered 'No (N)'	System	16 Sep 2020 18:33:40
	System	16 Sep 2020 18:33:40

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-16T11:33:33', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'ff3ded3c-b0d2-4f9c-b6af-7ace053b4c8d' User entered 'None (1)'	System	16 Sep 2020 18:33:40
	System	16 Sep 2020 18:33:40

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-16T11:33:36', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'ff3ded3c-b0d2-4f9c-b6af-7ace053b4c8d' User entered '16 Sep 2020 11:33'	System	16 Sep 2020 18:33:40
	System	16 Sep 2020 18:33:40

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '16 Sep 2020 10:15'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '16 Sep 2020 12:45'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	16 Sep 2020 16:58:49
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-16T18:26:44', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '8b9e87de-c51a-4d3c-8692-06ca26627323'	System	17 Sep 2020 01:27:34
User entered 'Does not interfere with activity (2)'	System	17 Sep 2020 01:27:34

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-16T18:26:59', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '8b9e87de-c51a-4d3c-8692-06ca26627323' User entered 'No (N)'	System	17 Sep 2020 01:27:34
	System	17 Sep 2020 01:27:34

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-16T18:27:05', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '8b9e87de-c51a-4d3c-8692-06ca26627323' User entered 'No (N)'	System	17 Sep 2020 01:27:34
	System	17 Sep 2020 01:27:34

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-16T18:27:13', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '8b9e87de-c51a-4d3c-8692-06ca26627323' User entered 'None (1)'	System	17 Sep 2020 01:27:34
	System	17 Sep 2020 01:27:34

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-16T18:27:16', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '8b9e87de-c51a-4d3c-8692-06ca26627323' User entered '16 Sep 2020 18:27'	System	17 Sep 2020 01:27:34
	System	17 Sep 2020 01:27:34

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '16 Sep 2020 13:40'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	16 Sep 2020 16:58:49
User entered 'Day 2'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-17T16:03:48', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '7d2c7db9-b8aa-4b92-b079-61d1c5116bb4'	System	17 Sep 2020 23:04:00
User entered 'Does not interfere with activity (2)'	System	17 Sep 2020 23:04:00

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-17T16:03:51', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '7d2c7db9-b8aa-4b92-b079-61d1c5116bb4'	System	17 Sep 2020 23:04:00
User entered 'No (N)'	System	17 Sep 2020 23:04:00

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-17T16:03:53', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '7d2c7db9-b8aa-4b92-b079-61d1c5116bb4'	System	17 Sep 2020 23:04:00
User entered 'No (N)'	System	17 Sep 2020 23:04:00

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-17T16:03:55', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '7d2c7db9-b8aa-4b92-b079-61d1c5116bb4'	System	17 Sep 2020 23:04:00
User entered 'None (1)'	System	17 Sep 2020 23:04:00

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-17T16:03:58', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '7d2c7db9-b8aa-4b92-b079-61d1c5116bb4' User entered '17 Sep 2020 16:03'	System	17 Sep 2020 23:04:00
	System	17 Sep 2020 23:04:00

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	16 Sep 2020 16:58:49
User entered 'Day 3'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-18T12:15:36', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '5e92fa79-9b99-45a3-9444-fab9496f124e'	System	18 Sep 2020 19:15:50
User entered 'Does not interfere with activity (2)'	System	18 Sep 2020 19:15:50

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-18T12:15:39', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '5e92fa79-9b99-45a3-9444-fab9496f124e' User entered 'No (N)'	System	18 Sep 2020 19:15:50
	System	18 Sep 2020 19:15:50

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-18T12:15:40', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '5e92fa79-9b99-45a3-9444-fab9496f124e' User entered 'No (N)'	System	18 Sep 2020 19:15:50
	System	18 Sep 2020 19:15:50

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-18T12:15:43', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '5e92fa79-9b99-45a3-9444-fab9496f124e'	System	18 Sep 2020 19:15:50
User entered 'None (1)'	System	18 Sep 2020 19:15:50

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-18T12:15:45', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '5e92fa79-9b99-45a3-9444-fab9496f124e' User entered '18 Sep 2020 12:15'	System	18 Sep 2020 19:15:50
	System	18 Sep 2020 19:15:50

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	16 Sep 2020 16:58:49
User entered 'Day 4'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-19T18:02:59', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'd2e0e8c6-9ae7-4d12-b5e1-235755134951'	System	20 Sep 2020 01:03:15
User entered 'Does not interfere with activity (2)'	System	20 Sep 2020 01:03:15

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-19T18:03:02', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'd2e0e8c6-9ae7-4d12-b5e1-235755134951'	System	20 Sep 2020 01:03:15
User entered 'No (N)'	System	20 Sep 2020 01:03:15

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-19T18:03:05', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'd2e0e8c6-9ae7-4d12-b5e1-235755134951' User entered 'No (N)'	System	20 Sep 2020 01:03:15
	System	20 Sep 2020 01:03:15

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-19T18:03:07', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'd2e0e8c6-9ae7-4d12-b5e1-235755134951'	System	20 Sep 2020 01:03:15
User entered 'None (1)'	System	20 Sep 2020 01:03:15

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-19T18:03:11', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'd2e0e8c6-9ae7-4d12-b5e1-235755134951' User entered '19 Sep 2020 18:03'	System	20 Sep 2020 01:03:15
	System	20 Sep 2020 01:03:15

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	16 Sep 2020 16:58:49
User entered 'Day 5'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-20T12:01:39', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'df903e93-d0f5-4499-859a-f0573085689a'	System	20 Sep 2020 19:01:51
User entered 'Does not interfere with activity (2)'	System	20 Sep 2020 19:01:51

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-20T12:01:41', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'df903e93-d0f5-4499-859a-f0573085689a' User entered 'No (N)'	System	20 Sep 2020 19:01:51
	System	20 Sep 2020 19:01:51

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-20T12:01:44', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'df903e93-d0f5-4499-859a-f0573085689a' User entered 'No (N)'	System	20 Sep 2020 19:01:51
	System	20 Sep 2020 19:01:51

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-20T12:01:46', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'df903e93-d0f5-4499-859a-f0573085689a' User entered 'None (1)'	System	20 Sep 2020 19:01:51
	System	20 Sep 2020 19:01:51

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-20T12:01:49', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'df903e93-d0f5-4499-859a-f0573085689a' User entered '20 Sep 2020 12:01'	System	20 Sep 2020 19:01:51
	System	20 Sep 2020 19:01:51

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	16 Sep 2020 16:58:49
User entered 'Day 6'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-21T17:19:01', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'b86d6a86-ab79-4680-81d1-d14b86cc3d38'	System	22 Sep 2020 00:19:10
User entered 'Does not interfere with activity (2)'	System	22 Sep 2020 00:19:10

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-21T17:19:04', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'b86d6a86-ab79-4680-81d1-d14b86cc3d38'	System	22 Sep 2020 00:19:10
User entered 'No (N)'	System	22 Sep 2020 00:19:10

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-21T17:19:05', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'b86d6a86-ab79-4680-81d1-d14b86cc3d38'	System	22 Sep 2020 00:19:10
User entered 'No (N)'	System	22 Sep 2020 00:19:10

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-21T17:19:06', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'b86d6a86-ab79-4680-81d1-d14b86cc3d38'	System	22 Sep 2020 00:19:10
User entered 'None (1)'	System	22 Sep 2020 00:19:10

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-21T17:19:08', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'b86d6a86-ab79-4680-81d1-d14b86cc3d38'	System	22 Sep 2020 00:19:10
User entered '21 Sep 2020 17:19'	System	22 Sep 2020 00:19:10

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	16 Sep 2020 16:58:49
User entered 'Day 7'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-22T12:00:24', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'bfb25926-6626-4b6b-b904-72db45f0fb52'	System	22 Sep 2020 19:00:38
User entered 'None (1)'	System	22 Sep 2020 19:00:38

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-22T12:00:26', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'bfb25926-6626-4b6b-b904-72db45f0fb52'	System	22 Sep 2020 19:00:38
User entered 'No (N)'	System	22 Sep 2020 19:00:38

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-22T12:00:28', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'bfb25926-6626-4b6b-b904-72db45f0fb52' User entered 'No (N)'	System	22 Sep 2020 19:00:38
	System	22 Sep 2020 19:00:38

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-22T12:00:30', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'bfb25926-6626-4b6b-b904-72db45f0fb52'	System	22 Sep 2020 19:00:38
User entered 'None (1)'	System	22 Sep 2020 19:00:38

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-22T12:00:32', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'bfb25926-6626-4b6b-b904-72db45f0fb52' User entered '22 Sep 2020 12:00'	System	22 Sep 2020 19:00:38
	System	22 Sep 2020 19:00:38

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	16 Sep 2020 16:58:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-16T11:33:41', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'e9f5d8d0-d67c-49de-a0ce-5300c193fa76' User entered 'None (0)'	System	16 Sep 2020 18:33:58
	System	16 Sep 2020 18:33:58

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-16T11:33:43', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'e9f5d8d0-d67c-49de-a0ce-5300c193fa76' User entered 'None (0)'	System	16 Sep 2020 18:33:58
	System	16 Sep 2020 18:33:58

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-16T11:33:44', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'e9f5d8d0-d67c-49de-a0ce-5300c193fa76' User entered 'None (0)'	System	16 Sep 2020 18:33:58
	System	16 Sep 2020 18:33:58

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-16T11:33:46', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'e9f5d8d0-d67c-49de-a0ce-5300c193fa76' User entered 'None (0)'	System	16 Sep 2020 18:33:58
	System	16 Sep 2020 18:33:58

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-16T11:33:47', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'e9f5d8d0-d67c-49de-a0ce-5300c193fa76' User entered 'None (0)'	System	16 Sep 2020 18:33:58
	System	16 Sep 2020 18:33:58

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-16T11:33:48', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'e9f5d8d0-d67c-49de-a0ce-5300c193fa76' User entered 'None (0)'	System	16 Sep 2020 18:33:58
	System	16 Sep 2020 18:33:58

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

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)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-16T11:33:53', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'e9f5d8d0-d67c-49de-a0ce-5300c193fa76' User entered 'No (N)'	System	16 Sep 2020 18:33:58
	System	16 Sep 2020 18:33:58

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-16T11:33:56', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'e9f5d8d0-d67c-49de-a0ce-5300c193fa76' User entered '16 Sep 2020 11:33'	System	16 Sep 2020 18:33:58
	System	16 Sep 2020 18:33:58

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '16 Sep 2020 10:15'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '16 Sep 2020 12:45'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	16 Sep 2020 16:58:49
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-16T18:27:20', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'ab7b4c81-5bdb-4445-ab58-3d953a81c0d5' User entered 'None (0)'	System	17 Sep 2020 01:27:42
	System	17 Sep 2020 01:27:42

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-16T18:27:22', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'ab7b4c81-5bdb-4445-ab58-3d953a81c0d5' User entered 'None (0)'	System	17 Sep 2020 01:27:42
	System	17 Sep 2020 01:27:42

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-16T18:27:24', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'ab7b4c81-5bdb-4445-ab58-3d953a81c0d5' User entered 'None (0)'	System	17 Sep 2020 01:27:42
	System	17 Sep 2020 01:27:42

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-16T18:27:26', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'ab7b4c81-5bdb-4445-ab58-3d953a81c0d5' User entered 'None (0)'	System	17 Sep 2020 01:27:42
	System	17 Sep 2020 01:27:42

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-16T18:27:27', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'ab7b4c81-5bdb-4445-ab58-3d953a81c0d5' User entered 'None (0)'	System	17 Sep 2020 01:27:42
	System	17 Sep 2020 01:27:42

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-16T18:27:31', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'ab7b4c81-5bdb-4445-ab58-3d953a81c0d5'	System	17 Sep 2020 01:27:42
User entered 'None (0)'	System	17 Sep 2020 01:27:42

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

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)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-16T18:27:34', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'ab7b4c81-5bdb-4445-ab58-3d953a81c0d5'	System	17 Sep 2020 01:27:42
User entered 'No (N)'	System	17 Sep 2020 01:27:42

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-16T18:27:37', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'ab7b4c81-5bdb-4445-ab58-3d953a81c0d5'	System	17 Sep 2020 01:27:42
User entered '16 Sep 2020 18:27'	System	17 Sep 2020 01:27:42

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '16 Sep 2020 13:40'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	16 Sep 2020 16:58:49
User entered 'Day 2'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-17T16:04:06', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'c717d42c-abd0-4b56-b45d-8ae70cbf8aa1'	System	17 Sep 2020 23:04:42
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	17 Sep 2020 23:04:42

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-17T16:04:10', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'c717d42c-abd0-4b56-b45d-8ae70cbf8aa1' User entered 'Significant; prevents daily activity (3)'	System	17 Sep 2020 23:04:42
	System	17 Sep 2020 23:04:42

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-17T16:04:18', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'c717d42c-abd0-4b56-b45d-8ae70cbf8aa1' User entered 'None (0)'	System	17 Sep 2020 23:04:42
	System	17 Sep 2020 23:04:42

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-17T16:04:21', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'c717d42c-abd0-4b56-b45d-8ae70cbf8aa1' User entered 'None (0)'	System	17 Sep 2020 23:04:42
	System	17 Sep 2020 23:04:42

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-17T16:04:24', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'c717d42c-abd0-4b56-b45d-8ae70cbf8aa1' User entered 'None (0)'	System	17 Sep 2020 23:04:42
	System	17 Sep 2020 23:04:42

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-17T16:04:30', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'c717d42c-abd0-4b56-b45d-8ae70cbf8aa1'	System	17 Sep 2020 23:04:42
User entered 'Some interference with activity not requiring medical attention (2)'	System	17 Sep 2020 23:04:42

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:56

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)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-17T16:04:36', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'c717d42c-abd0-4b56-b45d-8ae70cbf8aa1' User entered 'No (N)'	System	17 Sep 2020 23:04:42
	System	17 Sep 2020 23:04:42

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-17T16:04:39', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'c717d42c-abd0-4b56-b45d-8ae70cbf8aa1' User entered '17 Sep 2020 16:04'	System	17 Sep 2020 23:04:42
	System	17 Sep 2020 23:04:42

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	16 Sep 2020 16:58:49
User entered 'Day 3'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-18T12:15:52', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'dfd7acf3-2c2d-49b8-ba33-443a00cce77a'	System	18 Sep 2020 19:16:25
User entered 'No interference with activity (1)'	System	18 Sep 2020 19:16:25

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-18T12:15:58', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'dfd7acf3-2c2d-49b8-ba33-443a00cce77a'	System	18 Sep 2020 19:16:25
User entered 'Some interference with activity (2)'	System	18 Sep 2020 19:16:25

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-18T12:16:01', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'dfd7acf3-2c2d-49b8-ba33-443a00cce77a' User entered 'None (0)'	System	18 Sep 2020 19:16:25
	System	18 Sep 2020 19:16:25

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-18T12:16:03', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'dfd7acf3-2c2d-49b8-ba33-443a00cce77a' User entered 'None (0)'	System	18 Sep 2020 19:16:25
	System	18 Sep 2020 19:16:25

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-18T12:16:15', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'dfd7acf3-2c2d-49b8-ba33-443a00cce77a' User entered 'None (0)'	System	18 Sep 2020 19:16:25
	System	18 Sep 2020 19:16:25

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-18T12:16:17', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'dfd7acf3-2c2d-49b8-ba33-443a00cce77a' User entered 'None (0)'	System	18 Sep 2020 19:16:25
	System	18 Sep 2020 19:16:25

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:56

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)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-18T12:16:20', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'dfd7acf3-2c2d-49b8-ba33-443a00cce77a' User entered 'No (N)'	System	18 Sep 2020 19:16:25
	System	18 Sep 2020 19:16:25

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-18T12:16:22', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'dfd7acf3-2c2d-49b8-ba33-443a00cce77a' User entered '18 Sep 2020 12:16'	System	18 Sep 2020 19:16:25
	System	18 Sep 2020 19:16:25

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	16 Sep 2020 16:58:49
User entered 'Day 4'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-19T18:03:15', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '544b80ce-5cec-4e1e-a968-76fe654a2efa' User entered 'None (0)'	System	20 Sep 2020 01:03:38
	System	20 Sep 2020 01:03:38

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-19T18:03:17', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '544b80ce-5cec-4e1e-a968-76fe654a2efa' User entered 'None (0)'	System	20 Sep 2020 01:03:38
	System	20 Sep 2020 01:03:38

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-19T18:03:20', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '544b80ce-5cec-4e1e-a968-76fe654a2efa' User entered 'None (0)'	System	20 Sep 2020 01:03:38
	System	20 Sep 2020 01:03:38

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-19T18:03:22', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '544b80ce-5cec-4e1e-a968-76fe654a2efa' User entered 'None (0)'	System	20 Sep 2020 01:03:38
	System	20 Sep 2020 01:03:38

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-19T18:03:24', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '544b80ce-5cec-4e1e-a968-76fe654a2efa' User entered 'None (0)'	System	20 Sep 2020 01:03:38
	System	20 Sep 2020 01:03:38

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-19T18:03:27', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '544b80ce-5cec-4e1e-a968-76fe654a2efa' User entered 'None (0)'	System	20 Sep 2020 01:03:38
	System	20 Sep 2020 01:03:38

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:56

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)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-19T18:03:31', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '544b80ce-5cec-4e1e-a968-76fe654a2efa' User entered 'No (N)'	System	20 Sep 2020 01:03:38
	System	20 Sep 2020 01:03:38

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-19T18:03:33', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '544b80ce-5cec-4e1e-a968-76fe654a2efa' User entered '19 Sep 2020 18:03'	System	20 Sep 2020 01:03:38
	System	20 Sep 2020 01:03:38

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	16 Sep 2020 16:58:49
User entered 'Day 5'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-20T12:01:57', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'ed1d38b9-5bbb-4673-85a4-a59ca85726a1' User entered 'None (0)'	System	20 Sep 2020 19:02:23
	System	20 Sep 2020 19:02:23

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-20T12:01:59', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'ed1d38b9-5bbb-4673-85a4-a59ca85726a1' User entered 'None (0)'	System	20 Sep 2020 19:02:23
	System	20 Sep 2020 19:02:23

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-20T12:02:07', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'ed1d38b9-5bbb-4673-85a4-a59ca85726a1' User entered 'None (0)'	System	20 Sep 2020 19:02:23
	System	20 Sep 2020 19:02:23

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-20T12:02:08', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'ed1d38b9-5bbb-4673-85a4-a59ca85726a1' User entered 'None (0)'	System	20 Sep 2020 19:02:23
	System	20 Sep 2020 19:02:23

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-20T12:02:10', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'ed1d38b9-5bbb-4673-85a4-a59ca85726a1' User entered 'None (0)'	System	20 Sep 2020 19:02:23
	System	20 Sep 2020 19:02:23

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-20T12:02:11', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'ed1d38b9-5bbb-4673-85a4-a59ca85726a1' User entered 'None (0)'	System	20 Sep 2020 19:02:23
	System	20 Sep 2020 19:02:23

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:56

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)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-20T12:02:13', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'ed1d38b9-5bbb-4673-85a4-a59ca85726a1' User entered 'No (N)'	System	20 Sep 2020 19:02:23
	System	20 Sep 2020 19:02:23

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-20T12:02:18', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'ed1d38b9-5bbb-4673-85a4-a59ca85726a1' User entered '20 Sep 2020 12:02'	System	20 Sep 2020 19:02:23
	System	20 Sep 2020 19:02:23

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	16 Sep 2020 16:58:49
User entered 'Day 6'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-21T17:19:12', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'c055e871-3d92-4ed1-91fb-0b80b97d4dcf' User entered 'None (0)'	System	22 Sep 2020 00:19:27
	System	22 Sep 2020 00:19:27

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-21T17:19:14', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'c055e871-3d92-4ed1-91fb-0b80b97d4dcf' User entered 'None (0)'	System	22 Sep 2020 00:19:27
	System	22 Sep 2020 00:19:27

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-21T17:19:15', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'c055e871-3d92-4ed1-91fb-0b80b97d4dcf' User entered 'None (0)'	System	22 Sep 2020 00:19:27
	System	22 Sep 2020 00:19:27

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-21T17:19:16', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'c055e871-3d92-4ed1-91fb-0b80b97d4dcf' User entered 'None (0)'	System	22 Sep 2020 00:19:27
	System	22 Sep 2020 00:19:27

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-21T17:19:18', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'c055e871-3d92-4ed1-91fb-0b80b97d4dcf' User entered 'None (0)'	System	22 Sep 2020 00:19:27
	System	22 Sep 2020 00:19:27

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-21T17:19:19', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'c055e871-3d92-4ed1-91fb-0b80b97d4dcf' User entered 'None (0)'	System	22 Sep 2020 00:19:27
	System	22 Sep 2020 00:19:27

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:56

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)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-21T17:19:21', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'c055e871-3d92-4ed1-91fb-0b80b97d4dcf' User entered 'No (N)'	System	22 Sep 2020 00:19:27
	System	22 Sep 2020 00:19:27

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-21T17:19:24', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'c055e871-3d92-4ed1-91fb-0b80b97d4dcf' User entered '21 Sep 2020 17:19'	System	22 Sep 2020 00:19:27
	System	22 Sep 2020 00:19:27

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	16 Sep 2020 16:58:49
User entered 'Day 7'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-22T12:00:36', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '36045a18-0d56-4d65-bfc2-966338213f5f' User entered 'None (0)'	System	22 Sep 2020 19:00:51
	System	22 Sep 2020 19:00:51

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-22T12:00:37', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '36045a18-0d56-4d65-bfc2-966338213f5f' User entered 'None (0)'	System	22 Sep 2020 19:00:51
	System	22 Sep 2020 19:00:51

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-22T12:00:39', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '36045a18-0d56-4d65-bfc2-966338213f5f' User entered 'None (0)'	System	22 Sep 2020 19:00:51
	System	22 Sep 2020 19:00:51

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-22T12:00:41', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '36045a18-0d56-4d65-bfc2-966338213f5f' User entered 'None (0)'	System	22 Sep 2020 19:00:51
	System	22 Sep 2020 19:00:51

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-22T12:00:42', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '36045a18-0d56-4d65-bfc2-966338213f5f' User entered 'None (0)'	System	22 Sep 2020 19:00:51
	System	22 Sep 2020 19:00:51

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-22T12:00:44', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '36045a18-0d56-4d65-bfc2-966338213f5f' User entered 'None (0)'	System	22 Sep 2020 19:00:51
	System	22 Sep 2020 19:00:51

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:56

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)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-22T12:00:46', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '36045a18-0d56-4d65-bfc2-966338213f5f' User entered 'No (N)'	System	22 Sep 2020 19:00:51
	System	22 Sep 2020 19:00:51

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-09-22T12:00:48', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '36045a18-0d56-4d65-bfc2-966338213f5f' User entered '22 Sep 2020 12:00'	System	22 Sep 2020 19:00:51
	System	22 Sep 2020 19:00:51

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 16:58:49

US3732094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:29:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 16:58:49

US3732094

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	(b) (4) Sylvia Lindholm (b) (4)	24 Sep 2020 20:14:13

US3732094

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '24 Sep 2020'	(b) (4) Sylvia Lindholm (b) (4)	24 Sep 2020 20:14:13

US3732094

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sylvia Lindholm (b) (4)	24 Sep 2020 20:14:13

US3732094

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	(b) (4) Sylvia Lindholm (b) (4)	24 Sep 2020 20:14:13

US3732094

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	(b) (4) Sylvia Lindholm (b) (4)	24 Sep 2020 20:14:27

US3732094

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'I'	System	24 Sep 2020 20:14:27

US3732094

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Linda Vega (b) (4)	30 Sep 2020 17:19:54

US3732094

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '30 Sep 2020'	Linda Vega (b) (4)	30 Sep 2020 17:19:54

US3732094

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4)	30 Sep 2020 17:19:54

US3732094

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Linda Vega (b) (4)	30 Sep 2020 17:19:54

US3732094

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Linda Vega (b) (4)	30 Sep 2020 17:19:46

US3732094

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'I'	System	30 Sep 2020 17:19:46

US3732094

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	(b) (4) Sylvia Lindholm (b) (4)	07 Oct 2020 17:44:34

US3732094

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '7 Oct 2020'	(b) (4) Sylvia Lindholm (b) (4)	07 Oct 2020 17:44:34

US3732094

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sylvia Lindholm (b) (4)	07 Oct 2020 17:44:34

US3732094

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	(b) (4) Sylvia Lindholm (b) (4)	07 Oct 2020 17:44:34

US3732094

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	(b) (4) Sylvia Lindholm (b) (4)	07 Oct 2020 17:44:39

US3732094

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'I'	System	07 Oct 2020 17:44:39

US3732094

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Amara Yilmaz (b) (4)	20 Oct 2020 22:17:19

US3732094

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:56

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '20 Oct 2020'	Amara Yilmaz (b) (4)	20 Oct 2020 22:17:19

US3732094

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:56

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Clinic (Clinic)'	Amara Yilmaz (b) (4)	20 Oct 2020 22:17:19

US3732094

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'VISIT3'	System	20 Oct 2020 22:17:19

US3732094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Amara Yilmaz (b) (4)	20 Oct 2020 22:20:23

US3732094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '20 Oct 2020'	Amara Yilmaz (b) (4)	20 Oct 2020 22:20:23

US3732094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '09:14'	Amara Yilmaz (b) (4)	20 Oct 2020 22:20:23

US3732094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered '20 Oct 2020 09:14'	System	20 Oct 2020 22:20:23

US3732094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '98.2' F	Amara Yilmaz (b) (4)	20 Oct 2020 22:20:23

US3732094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Oral (Oral)'	Amara Yilmaz (b) (4)	20 Oct 2020 22:20:23

US3732094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Amara Yilmaz (b) (4)	20 Oct 2020 22:20:23

US3732094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '72'	Amara Yilmaz (b) (4)	20 Oct 2020 22:20:23

US3732094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'bpm'	System	20 Oct 2020 22:20:23

US3732094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '16'	Amara Yilmaz (b) (4)	20 Oct 2020 22:20:23

US3732094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'breaths/min'	System	20 Oct 2020 22:20:23

US3732094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '146'	Amara Yilmaz (b) (4)	20 Oct 2020 22:20:23

US3732094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'mmHg'	System	20 Oct 2020 22:20:23

US3732094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '81'	Amara Yilmaz (b) (4)	20 Oct 2020 22:20:23

US3732094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'mmHg'	System	20 Oct 2020 22:20:23

US3732094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21

US3732094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21

US3732094

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Amara Yilmaz (b) (4)	20 Oct 2020 22:18:53

US3732094

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '20 Oct 2020'	Amara Yilmaz (b) (4)	20 Oct 2020 22:18:53

US3732094

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Amara Yilmaz (b) (4)	20 Oct 2020 22:19:20

US3732094

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:56

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '20 Oct 2020'	Amara Yilmaz (b) (4)	20 Oct 2020 22:19:20

US3732094

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:56

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '09:14'	Amara Yilmaz (b) (4)	20 Oct 2020 22:19:20

US3732094

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered '20 Oct 2020 09:14'	System	20 Oct 2020 22:19:20

US3732094

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Amara Yilmaz (b) (4)	20 Oct 2020 22:19:42

US3732094

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered '1'	System	20 Oct 2020 22:19:42

US3732094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered 'Day 64'	System	19 Aug 2020 18:05:17

US3732094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-10-19T11:44:33', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '7b7557e6-03c0-4142-8110-f41b993fb190'	System	19 Oct 2020 18:44:47
User entered 'No (N)'	System	19 Oct 2020 18:44:47

US3732094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-10-19T11:44:35', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '7b7557e6-03c0-4142-8110-f41b993fb190'	System	19 Oct 2020 18:44:47
User entered 'No (N)'	System	19 Oct 2020 18:44:47

US3732094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-10-19T11:44:43', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '7b7557e6-03c0-4142-8110-f41b993fb190' User entered '19 Oct 2020 11:44:43'	System	19 Oct 2020 18:44:47
	System	19 Oct 2020 18:44:47

US3732094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered '19 Oct 2020 00:01'	System	19 Aug 2020 18:05:17

US3732094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered '23 Oct 2020 23:59'	System	19 Aug 2020 18:05:17

US3732094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered 'Day 71'	System	19 Aug 2020 18:05:17

US3732094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-10-28T12:01:06', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '318bfe9d-377c-4b50-b83a-b44ffc7fd342'	System	28 Oct 2020 19:01:17
User entered 'No (N)'	System	28 Oct 2020 19:01:17

US3732094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-10-28T12:01:10', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '318bfe9d-377c-4b50-b83a-b44ffc7fd342'	System	28 Oct 2020 19:01:17
User entered 'No (N)'	System	28 Oct 2020 19:01:17

US3732094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-10-28T12:01:13', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '318bfe9d-377c-4b50-b83a-b44ffc7fd342' User entered '28 Oct 2020 12:01:13'	System	28 Oct 2020 19:01:17
	System	28 Oct 2020 19:01:17

US3732094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered '26 Oct 2020 00:01'	System	19 Aug 2020 18:05:17

US3732094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered '30 Oct 2020 23:59'	System	19 Aug 2020 18:05:17

US3732094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered 'Day 78'	System	19 Aug 2020 18:05:17

US3732094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-11-05T06:19:52', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '35fd4a37-23c1-4b56-8d0c-5370012c553d' User entered 'No (N)'	System	05 Nov 2020 14:20:04
	System	05 Nov 2020 14:20:04

US3732094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-11-05T06:19:55', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '35fd4a37-23c1-4b56-8d0c-5370012c553d' User entered 'No (N)'	System	05 Nov 2020 14:20:04
	System	05 Nov 2020 14:20:04

US3732094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-11-05T06:19:58', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '35fd4a37-23c1-4b56-8d0c-5370012c553d' User entered '05 Nov 2020 06:19:58'	System	05 Nov 2020 14:20:04
	System	05 Nov 2020 14:20:04

US3732094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered '02 Nov 2020 00:01'	System	19 Aug 2020 18:05:17

US3732094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered '06 Nov 2020 23:59'	System	19 Aug 2020 18:05:17

US3732094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered 'Day 92'	System	19 Aug 2020 18:05:17

US3732094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-11-16T20:42:39', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '14d256b3-89d0-4953-a456-2b89c61ae497'	System	17 Nov 2020 04:42:51
User entered 'No (N)'	System	17 Nov 2020 04:42:51

US3732094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-11-16T20:42:42', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '14d256b3-89d0-4953-a456-2b89c61ae497'	System	17 Nov 2020 04:42:51
User entered 'No (N)'	System	17 Nov 2020 04:42:51

US3732094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-11-16T20:42:46', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '14d256b3-89d0-4953-a456-2b89c61ae497'	System	17 Nov 2020 04:42:51
User entered '16 Nov 2020 20:42:46'	System	17 Nov 2020 04:42:51

US3732094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered '16 Nov 2020 00:01'	System	19 Aug 2020 18:05:17

US3732094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:14:10
Data entry locked.	System	19 Aug 2020 18:05:17
User entered '20 Nov 2020 23:59'	System	19 Aug 2020 18:05:17

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-11-21T13:22:26', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'f607bf5b-73e7-4030-b9fb-b24c84dcf3bc'	System	21 Nov 2020 21:22:40
User entered 'No (N)'	System	21 Nov 2020 21:22:40

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-11-21T13:22:30', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'f607bf5b-73e7-4030-b9fb-b24c84dcf3bc'	System	21 Nov 2020 21:22:40
User entered 'No (N)'	System	21 Nov 2020 21:22:40

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-11-21T13:22:34', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'f607bf5b-73e7-4030-b9fb-b24c84dcf3bc' User entered '21 Nov 2020 13:22:34'	System	21 Nov 2020 21:22:40
	System	21 Nov 2020 21:22:40

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-11-27T14:41:46', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'ad94913d-590b-4098-b0bb-8ce687b8166b'	System	27 Nov 2020 22:41:56
User entered 'No (N)'	System	27 Nov 2020 22:41:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-11-27T14:41:50', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'ad94913d-590b-4098-b0bb-8ce687b8166b'	System	27 Nov 2020 22:41:56
User entered 'No (N)'	System	27 Nov 2020 22:41:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-11-27T14:41:52', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'ad94913d-590b-4098-b0bb-8ce687b8166b' User entered '27 Nov 2020 14:41:52'	System	27 Nov 2020 22:41:56
	System	27 Nov 2020 22:41:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-12-06T12:00:15', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '6a9079d3-72d7-4bf3-a38c-1584781041a5'	System	06 Dec 2020 20:00:27
User entered 'No (N)'	System	06 Dec 2020 20:00:27

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-12-06T12:00:18', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '6a9079d3-72d7-4bf3-a38c-1584781041a5'	System	06 Dec 2020 20:00:27
User entered 'No (N)'	System	06 Dec 2020 20:00:27

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-12-06T12:00:24', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '6a9079d3-72d7-4bf3-a38c-1584781041a5' User entered '06 Dec 2020 12:00:24'	System	06 Dec 2020 20:00:27
	System	06 Dec 2020 20:00:27

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-12-14T17:59:19', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '9cf74cd1-a7f5-433f-995a-8563a9fb7776'	System	15 Dec 2020 01:59:26
User entered 'No (N)'	System	15 Dec 2020 01:59:26

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-12-14T17:59:20', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '9cf74cd1-a7f5-433f-995a-8563a9fb7776'	System	15 Dec 2020 01:59:26
User entered 'No (N)'	System	15 Dec 2020 01:59:26

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-12-14T17:59:24', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '9cf74cd1-a7f5-433f-995a-8563a9fb7776' User entered '14 Dec 2020 17:59:24'	System	15 Dec 2020 01:59:26
	System	15 Dec 2020 01:59:26

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-12-18T16:55:21', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '61755764-bd55-4c2f-a3b0-d2e7f7c2b695'	System	19 Dec 2020 00:55:33
User entered 'No (N)'	System	19 Dec 2020 00:55:33

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-12-18T16:55:25', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '61755764-bd55-4c2f-a3b0-d2e7f7c2b695'	System	19 Dec 2020 00:55:33
User entered 'No (N)'	System	19 Dec 2020 00:55:33

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-12-18T16:55:30', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '61755764-bd55-4c2f-a3b0-d2e7f7c2b695'	System	19 Dec 2020 00:55:33
User entered '18 Dec 2020 16:55:30'	System	19 Dec 2020 00:55:33

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-12-25T09:26:07', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '67770829-e5dd-4fc3-b8bd-5d3f776a5302'	System	25 Dec 2020 17:26:49
User entered 'Yes (Y)'	System	25 Dec 2020 17:26:49

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-12-25T09:26:10', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '67770829-e5dd-4fc3-b8bd-5d3f776a5302'	System	25 Dec 2020 17:26:49
User entered 'No (N)'	System	25 Dec 2020 17:26:49

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-12-25T09:26:15', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '67770829-e5dd-4fc3-b8bd-5d3f776a5302'	System	25 Dec 2020 17:26:49
User entered 'No (N)'	System	25 Dec 2020 17:26:49

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-12-25T09:26:22', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '67770829-e5dd-4fc3-b8bd-5d3f776a5302'	System	25 Dec 2020 17:26:49
User entered 'Yes (Y)'	System	25 Dec 2020 17:26:49

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-12-25T09:26:31', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '67770829-e5dd-4fc3-b8bd-5d3f776a5302'	System	25 Dec 2020 17:26:49
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Dec 2020 17:26:49

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2020-12-25T09:26:39', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '67770829-e5dd-4fc3-b8bd-5d3f776a5302' User entered '25 Dec 2020 09:26:39'	System	25 Dec 2020 17:26:49
	System	25 Dec 2020 17:26:49

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-01-02T11:28:02', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'c7d71e0b-6836-4039-8fa7-e1e8a2b7800e' User entered 'No (N)'	System	02 Jan 2021 19:28:19
	System	02 Jan 2021 19:28:19

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-01-02T11:28:10', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'c7d71e0b-6836-4039-8fa7-e1e8a2b7800e' User entered 'No (N)'	System	02 Jan 2021 19:28:19

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-01-02T11:28:16', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'c7d71e0b-6836-4039-8fa7-e1e8a2b7800e' User entered '02 Jan 2021 11:28:16'	System	02 Jan 2021 19:28:19
	System	02 Jan 2021 19:28:19

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-01-10T12:00:27', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'dd7fc5a6-ddf4-4f95-993d-8abf25861c5d'	System	10 Jan 2021 20:00:42
User entered 'No (N)'	System	10 Jan 2021 20:00:42

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-01-10T12:00:30', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'dd7fc5a6-ddf4-4f95-993d-8abf25861c5d'	System	10 Jan 2021 20:00:42
User entered 'No (N)'	System	10 Jan 2021 20:00:42

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-01-10T12:00:33', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'dd7fc5a6-ddf4-4f95-993d-8abf25861c5d' User entered '10 Jan 2021 12:00:33'	System	10 Jan 2021 20:00:42
	System	10 Jan 2021 20:00:42

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-01-18T09:55:52', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'bfb1f20a-6998-48e4-89e6-221f58dc332c'	System	19 Jan 2021 20:15:13
User entered 'No (N)'	System	19 Jan 2021 20:15:13

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-01-18T09:55:54', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'bfb1f20a-6998-48e4-89e6-221f58dc332c'	System	19 Jan 2021 20:15:13
User entered 'No (N)'	System	19 Jan 2021 20:15:13

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-01-18T09:55:57', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'bfb1f20a-6998-48e4-89e6-221f58dc332c'	System	19 Jan 2021 20:15:13
User entered '18 Jan 2021 09:55:57'	System	19 Jan 2021 20:15:13

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-01-29T00:04:51', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '0b5f3025-6a3a-4ee6-bad2-7b063bc87c3d'	System	29 Jan 2021 08:05:00
User entered 'No (N)'	System	29 Jan 2021 08:05:00

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-01-29T00:04:53', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '0b5f3025-6a3a-4ee6-bad2-7b063bc87c3d'	System	29 Jan 2021 08:05:00
User entered 'No (N)'	System	29 Jan 2021 08:05:00

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-01-29T00:04:58', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '0b5f3025-6a3a-4ee6-bad2-7b063bc87c3d' User entered '29 Jan 2021 00:04:58'	System	29 Jan 2021 08:05:00
	System	29 Jan 2021 08:05:00

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-02-05T22:49:15', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'ae5326e7-4916-40c6-81ea-5d1dd88f53cb' User entered 'No (N)'	System	06 Feb 2021 06:49:26

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-02-05T22:49:18', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'ae5326e7-4916-40c6-81ea-5d1dd88f53cb' User entered 'No (N)'	System	06 Feb 2021 06:49:26

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-02-05T22:49:20', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'ae5326e7-4916-40c6-81ea-5d1dd88f53cb' User entered '05 Feb 2021 22:49:20'	System	06 Feb 2021 06:49:26
	System	06 Feb 2021 06:49:26

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-02-12T11:49:55', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '92b65606-124c-4019-8a68-9925648660c6' User entered 'No (N)'	System	12 Feb 2021 19:50:06
	System	12 Feb 2021 19:50:06

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-02-12T11:49:58', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '92b65606-124c-4019-8a68-9925648660c6'	System	12 Feb 2021 19:50:06
User entered 'No (N)'	System	12 Feb 2021 19:50:06

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-02-12T11:50:02', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '92b65606-124c-4019-8a68-9925648660c6'	System	12 Feb 2021 19:50:06
User entered '12 Feb 2021 11:50:02'	System	12 Feb 2021 19:50:06

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-02-19T07:40:05', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '06c23b57-bba9-4961-a194-c08530a2eebc' User entered 'No (N)'	System	19 Feb 2021 15:40:16
	System	19 Feb 2021 15:40:16

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-02-19T07:40:07', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '06c23b57-bba9-4961-a194-c08530a2eebc' User entered 'No (N)'	System	19 Feb 2021 15:40:16

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-02-19T07:40:10', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '06c23b57-bba9-4961-a194-c08530a2eebc' User entered '19 Feb 2021 07:40:10'	System	19 Feb 2021 15:40:16
	System	19 Feb 2021 15:40:16

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-02-27T15:37:52', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '8f7cfd9d-90f3-42b9-836a-36d15d0967e2'	System	27 Feb 2021 23:38:31
User entered 'Yes (Y)'	System	27 Feb 2021 23:38:31

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-02-27T15:37:56', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '8f7cfd9d-90f3-42b9-836a-36d15d0967e2'	System	27 Feb 2021 23:38:31
User entered 'No (N)'	System	27 Feb 2021 23:38:31

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-02-27T15:38:02', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '8f7cfd9d-90f3-42b9-836a-36d15d0967e2' User entered 'No (N)'	System	27 Feb 2021 23:38:31

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-02-27T15:38:11', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '8f7cfd9d-90f3-42b9-836a-36d15d0967e2'	System	27 Feb 2021 23:38:31
User entered 'Yes (Y)'	System	27 Feb 2021 23:38:31

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-02-27T15:38:16', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '8f7cfd9d-90f3-42b9-836a-36d15d0967e2'	System	27 Feb 2021 23:38:31
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Feb 2021 23:38:31

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-02-27T15:38:21', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '8f7cfd9d-90f3-42b9-836a-36d15d0967e2'	System	27 Feb 2021 23:38:31
User entered '27 Feb 2021 15:38:21'	System	27 Feb 2021 23:38:31

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-03-05T00:03:55-08:00', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '57ca9023-3249-4308-a68e-579dcf13a8ad'	System	05 Mar 2021 08:04:31
User entered 'Yes (Y)'	System	05 Mar 2021 08:04:31

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-03-05T00:04:00-08:00', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '57ca9023-3249-4308-a68e-579dcf13a8ad'	System	05 Mar 2021 08:04:31
User entered 'No (N)'	System	05 Mar 2021 08:04:31

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-03-05T00:04:04-08:00', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '57ca9023-3249-4308-a68e-579dcf13a8ad'	System	05 Mar 2021 08:04:31
User entered 'No (N)'	System	05 Mar 2021 08:04:31

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-03-05T00:04:11-08:00', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '57ca9023-3249-4308-a68e-579dcf13a8ad'	System	05 Mar 2021 08:04:31
User entered 'Yes (Y)'	System	05 Mar 2021 08:04:31

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-03-05T00:04:18-08:00', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '57ca9023-3249-4308-a68e-579dcf13a8ad'	System	05 Mar 2021 08:04:31
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Mar 2021 08:04:31

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-03-05T00:04:21-08:00', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '57ca9023-3249-4308-a68e-579dcf13a8ad' User entered '05 Mar 2021 00:04:21'	System	05 Mar 2021 08:04:31
	System	05 Mar 2021 08:04:31

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-03-12T19:46:25-08:00', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '083c9b9a-46a0-4094-b50b-55a4ea833f77'	System	13 Mar 2021 03:46:42
User entered 'No (N)'	System	13 Mar 2021 03:46:42

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-03-12T19:46:28-08:00', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '083c9b9a-46a0-4094-b50b-55a4ea833f77'	System	13 Mar 2021 03:46:42
User entered 'No (N)'	System	13 Mar 2021 03:46:42

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-03-12T19:46:33-08:00', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '083c9b9a-46a0-4094-b50b-55a4ea833f77'	System	13 Mar 2021 03:46:42
User entered '12 Mar 2021 19:46:33'	System	13 Mar 2021 03:46:42

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-03-19T15:50:33-07:00', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'ad305e19-00f3-4692-863e-7c8a1fb21a42'	System	19 Mar 2021 22:50:42
User entered 'No (N)'	System	19 Mar 2021 22:50:42

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-03-19T15:50:35-07:00', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'ad305e19-00f3-4692-863e-7c8a1fb21a42'	System	19 Mar 2021 22:50:42
User entered 'No (N)'	System	19 Mar 2021 22:50:42

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-03-19T15:50:38-07:00', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'ad305e19-00f3-4692-863e-7c8a1fb21a42'	System	19 Mar 2021 22:50:42
User entered '19 Mar 2021 15:50:38'	System	19 Mar 2021 22:50:42

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-03-26T15:00:55-07:00', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '751b41a8-d7f1-426a-b670-6336651e351d'	System	26 Mar 2021 22:03:28
User entered 'No (N)'	System	26 Mar 2021 22:03:28

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-03-26T15:00:57-07:00', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '751b41a8-d7f1-426a-b670-6336651e351d'	System	26 Mar 2021 22:03:28
User entered 'No (N)'	System	26 Mar 2021 22:03:28

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-03-26T15:01:00-07:00', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '751b41a8-d7f1-426a-b670-6336651e351d'	System	26 Mar 2021 22:03:28
User entered '26 Mar 2021 15:01:00'	System	26 Mar 2021 22:03:28

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-04-05T18:11:27-07:00', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'a8533c5c-a246-4ffe-8631-f006ea8d94cb' User entered 'No (N)'	System	06 Apr 2021 01:14:23
	System	06 Apr 2021 01:14:23

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-04-05T18:11:29-07:00', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'a8533c5c-a246-4ffe-8631-f006ea8d94cb' User entered 'No (N)'	System	06 Apr 2021 01:14:23

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-04-05T18:11:32-07:00', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'a8533c5c-a246-4ffe-8631-f006ea8d94cb' User entered '05 Apr 2021 18:11:32'	System	06 Apr 2021 01:14:23
	System	06 Apr 2021 01:14:23

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-04-12T10:26:34-07:00', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '3b09222b-744c-42f6-8a5e-fff2f501e2c4'	System	16 Apr 2021 13:17:13
User entered 'No (N)'	System	16 Apr 2021 13:17:13

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-04-12T10:26:36-07:00', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '3b09222b-744c-42f6-8a5e-fff2f501e2c4'	System	16 Apr 2021 13:17:13
User entered 'No (N)'	System	16 Apr 2021 13:17:13

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-04-12T10:26:39-07:00', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '3b09222b-744c-42f6-8a5e-fff2f501e2c4'	System	16 Apr 2021 13:17:13
User entered '12 Apr 2021 10:26:39'	System	16 Apr 2021 13:17:13

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-04-16T06:17:05-07:00', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'bb945ffa-c91a-43cd-b2fa-5218da0b6361'	System	16 Apr 2021 13:17:22
User entered 'No (N)'	System	16 Apr 2021 13:17:22

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-04-16T06:17:08-07:00', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'bb945ffa-c91a-43cd-b2fa-5218da0b6361'	System	16 Apr 2021 13:17:22
User entered 'No (N)'	System	16 Apr 2021 13:17:22

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-04-16T06:17:12-07:00', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: 'bb945ffa-c91a-43cd-b2fa-5218da0b6361'	System	16 Apr 2021 13:17:22
User entered '16 Apr 2021 06:17:12'	System	16 Apr 2021 13:17:22

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-04-23T05:32:33-07:00', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '6ef82600-9c12-45db-bad5-04548a499e4a'	System	23 Apr 2021 12:32:45
User entered 'No (N)'	System	23 Apr 2021 12:32:45

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-04-23T05:32:35-07:00', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '6ef82600-9c12-45db-bad5-04548a499e4a'	System	23 Apr 2021 12:32:45
User entered 'No (N)'	System	23 Apr 2021 12:32:45

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-04-23T05:32:38-07:00', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '6ef82600-9c12-45db-bad5-04548a499e4a'	System	23 Apr 2021 12:32:45
User entered '23 Apr 2021 05:32:38'	System	23 Apr 2021 12:32:45

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-04-30T01:50:35-07:00', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '6ab3aac0-6633-486c-b1af-356b80038b07'	System	30 Apr 2021 08:50:46
User entered 'No (N)'	System	30 Apr 2021 08:50:46

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-04-30T01:50:37-07:00', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '6ab3aac0-6633-486c-b1af-356b80038b07'	System	30 Apr 2021 08:50:46
User entered 'No (N)'	System	30 Apr 2021 08:50:46

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-04-30T01:50:41-07:00', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '6ab3aac0-6633-486c-b1af-356b80038b07' User entered '30 Apr 2021 01:50:41'	System	30 Apr 2021 08:50:46
	System	30 Apr 2021 08:50:46

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 23:06:56

US3732094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:06:56
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 23:06:56

US3732094

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:29:56

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)	25 Apr 2021 16:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-02-27T15:38:26', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '4e3c0e6a-c0d3-499e-b2a8-08b79c13ed16' User entered 'No (N)'	System	27 Feb 2021 23:38:35
	System	27 Feb 2021 23:38:35

US3732094

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:29:56

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E54F4D8F-07D6-4EBF-BD4F-465E083BD6E0)', Time: '2021-02-27T15:38:31', User OID: 'PatientReportedOutcome (US3732094)', ODM File OID: '4e3c0e6a-c0d3-499e-b2a8-08b79c13ed16' User entered '27 Feb 2021 15:38:31'	System	27 Feb 2021 23:38:35
	System	27 Feb 2021 23:38:35

US3732094

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Linda Vega (b) (4)	11 Nov 2020 20:23:36

US3732094

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '11 Nov 2020'	Linda Vega (b) (4)	11 Nov 2020 20:23:36

US3732094

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4)	11 Nov 2020 20:23:36

US3732094

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Linda Vega (b) (4)	11 Nov 2020 20:23:36

US3732094

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Linda Vega (b) (4)	11 Nov 2020 20:23:41

US3732094

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:31:21
User entered 'I'	System	11 Nov 2020 20:23:41

US3732094

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:20:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
User closed query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 14-Jan-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 11:15:10
Query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 14-Jan-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' answered with 'updated' (Site from DM).	Gordon Bovee (b) (4)	15 Mar 2021 19:05:18
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 14JAN2021 for the Participant Decision Visit, however, there is no data recorded for the Participant Decision Visit. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 12:24:43
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 14JAN2021 for the Participant Decision Visit, however, there is no data recorded for the Participant Decision Visit. Please clarify and update as appropriate. ' answered with 'updated' (Site from DM).	Gordon Bovee (b) (4)	17 Feb 2021 23:23:48

US3732094

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 14-Jan-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 07:02:13
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 14JAN2021 for the Participant Decision Visit, however, there is no data recorded for the Participant Decision Visit. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 20:08:15
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	16 Dec 2020 00:27:55

US3732094

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:20:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
	(b) (4)	
User entered '15 Dec 2020'	Linda Vega (b) (4)	16 Dec 2020 00:27:55
	(b) (4)	

US3732094

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:20:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4)	16 Dec 2020 00:27:55
	(b) (4)	

US3732094

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:20:14
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
	(b) (4)	
User entered empty.	Linda Vega (b) (4)	16 Dec 2020 00:27:55
	(b) (4)	

US3732094

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:20:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
	(b) (4)	
User entered 'Yes (Y)'	Linda Vega (b) (4)	16 Dec 2020 00:28:01
	(b) (4)	

US3732094

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:20:14
User entered 'I'	System	16 Dec 2020 00:28:01

US3732094

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:20:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
	(b) (4)	
User entered 'Yes (Y)'	Linda Vega (b) (4)	15 Feb 2021 22:21:56
	(b) (4)	

US3732094

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:20:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
	(b) (4)	
User entered '14 Jan 2021'	Linda Vega (b) (4)	15 Feb 2021 22:21:56
	(b) (4)	

US3732094

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:20:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4)	15 Feb 2021 22:21:56
	(b) (4)	

US3732094

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:20:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
	(b) (4)	
User entered empty.	Linda Vega (b) (4)	15 Feb 2021 22:21:56
	(b) (4)	

US3732094

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:20:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
	(b) (4)	
User entered 'Yes (Y)'	Linda Vega (b) (4)	15 Feb 2021 22:22:02
	(b) (4)	

US3732094

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:20:14
User entered 'I'	System	15 Feb 2021 22:22:02

US3732094

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:20:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
	(b) (4)	
User entered 'Yes (Y)'	Linda Vega (b) (4)	15 Feb 2021 22:22:16
	(b) (4)	

US3732094

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:20:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
	(b) (4)	
User entered '15 Feb 2021'	Linda Vega (b) (4)	15 Feb 2021 22:22:16
	(b) (4)	

US3732094

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:20:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4)	15 Feb 2021 22:22:16
	(b) (4)	

US3732094

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:20:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
	(b) (4)	
User entered empty.	Linda Vega (b) (4)	15 Feb 2021 22:22:16
	(b) (4)	

US3732094

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:20:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
	(b) (4)	
User entered 'Yes (Y)'	Linda Vega (b) (4)	15 Feb 2021 22:22:23
	(b) (4)	

US3732094

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:20:14
User entered 'I'	System	15 Feb 2021 22:22:23

US3732094

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
User entered 'Yes (Y)'	(b) (4) Gordon Bovee (b) (4)	15 Mar 2021 19:10:40

US3732094

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:56

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
User entered '15 Mar 2021'	(b) (4) Gordon Bovee (b) (4)	15 Mar 2021 19:10:40

US3732094

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:56

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
User entered 'Clinic (Clinic)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:10:40

US3732094

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'VISIT4'	System	15 Mar 2021 19:10:40

US3732094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:58:05
User entered 'Yes (Y)'	(b) (4) Makenna Orel (b) (4)	01 Apr 2021 19:05:14

US3732094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:58:05
User entered '15 Mar 2021'	(b) (4) Makenna Orel (b) (4)	01 Apr 2021 19:05:14

US3732094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:58:05
User entered '10:26'	(b) (4) Makenna Orel (b) (4) (b) (4)	01 Apr 2021 19:05:14

US3732094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered '15 Mar 2021 10:26'	System	01 Apr 2021 19:05:14

US3732094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:58:05
User entered '98.0' F	Makenna Orel (b) (4)	01 Apr 2021 19:05:14

US3732094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:58:05
User entered 'Oral (Oral)'	(b) (4) Makenna Orel (b) (4)	01 Apr 2021 19:05:14

US3732094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:58:05
User entered empty.	(b) (4) Makenna Orel (b) (4)	01 Apr 2021 19:05:14

US3732094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:58:05
User entered '61'	Makenna Orel (b) (4)	01 Apr 2021 19:05:14

US3732094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'bpm'	System	01 Apr 2021 19:05:14

US3732094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:58:05
User entered '17'	(b) (4) Makenna Orel (b) (4)	01 Apr 2021 19:05:14

US3732094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'breaths/min'	System	01 Apr 2021 19:05:14

US3732094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:58:05
User entered '142'	(b) (4) Makenna Orel (b) (4)	01 Apr 2021 19:05:14

US3732094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'mmHg'	System	01 Apr 2021 19:05:14

US3732094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:58:05
User entered '99'	(b) (4) Makenna Orel (b) (4)	01 Apr 2021 19:05:14

US3732094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'mmHg'	System	01 Apr 2021 19:05:14

US3732094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 05:33:09

US3732094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:56

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 05:33:09

US3732094

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
User entered 'Yes (Y)'	(b) (4) Gordon Bovee (b) (4)	15 Mar 2021 19:11:05

US3732094

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
User entered '15 Mar 2021'	(b) (4) Gordon Bovee (b) (4)	15 Mar 2021 19:11:05

US3732094

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
User entered 'Yes (Y)'	(b) (4) Gordon Bovee (b) (4)	15 Mar 2021 19:11:30

US3732094

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:56

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
User entered '15 Mar 2021'	Gordon Bovee (b) (4)	15 Mar 2021 19:11:30

US3732094

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:56

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
User entered '10:33'	(b) (4) Gordon Bovee (b) (4)	15 Mar 2021 19:11:30

US3732094

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered '15 Mar 2021 10:33'	System	15 Mar 2021 19:11:30

US3732094

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
User entered 'Yes (Y)'	(b) (4) Gordon Bovee (b) (4)	15 Mar 2021 19:11:48

US3732094

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:33:09
User entered 'I'	System	15 Mar 2021 19:11:48

US3732094

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
	(b) (4)	
User entered 'Yes (Y)'	Sylvia Lindholm (b) (4)	14 Apr 2021 22:51:37

US3732094

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
	(b) (4)	
User entered '14 Apr 2021'	Sylvia Lindholm (b) (4)	14 Apr 2021 22:51:37

US3732094

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sylvia Lindholm (b) (4)	14 Apr 2021 22:51:37

US3732094

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered empty.	(b) (4) Sylvia Lindholm (b) (4)	14 Apr 2021 22:51:37

US3732094

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
	(b) (4)	
User entered 'Yes (Y)'	Sylvia Lindholm (b) (4)	14 Apr 2021 22:51:41

US3732094

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:56

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 22:51:41

US3732094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:55:56
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	17 Feb 2021 23:20:01

US3732094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:56

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:55:56
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '14 Jan 2021'	Gordon Bovee (b) (4)	17 Feb 2021 23:20:01

US3732094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:56

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:55:56
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Clinic (Clinic)'	Gordon Bovee (b) (4)	17 Feb 2021 23:20:01

US3732094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:55:56
User entered 'UNBLND_DECIDE'	System	17 Feb 2021 23:20:01

US3732094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:29:56

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:55:56
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '14 Jan 2021'	Gordon Bovee (b) (4)	17 Feb 2021 23:20:24

US3732094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:29:56

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:55:56
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:47:59

US3732094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:29:56

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:55:56
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	17 Feb 2021 23:20:24

US3732094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:29:56

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:55:56
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:47:59

US3732094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:29:56

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:55:56
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '14 Jan 2021'	Gordon Bovee (b) (4)	17 Feb 2021 23:20:24

US3732094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:29:56

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:55:56
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'mRNA-1273 (mRNA-1273)'	Gordon Bovee (b) (4)	17 Feb 2021 23:20:24

US3732094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:29:56

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:55:56
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'mRNA-1273 (mRNA-1273)'	Gordon Bovee (b) (4)	17 Feb 2021 23:20:24

US3732094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:29:56

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:55:56
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'mRNA-1273 (mRNA-1273)'	Gordon Bovee (b) (4)	17 Feb 2021 23:20:24

US3732094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:29:56

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:55:56
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'No (N)'	Gordon Bovee (b) (4)	17 Feb 2021 23:20:24

US3732094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:29:56

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:55:56
User entered empty.	System	17 Feb 2021 23:20:24

US3732094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:29:56

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:55:56
User entered empty.	System	17 Feb 2021 23:20:24

US3732094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:55:56
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	17 Feb 2021 23:21:19

US3732094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:56

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:55:56
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '14 Jan 2021'	Gordon Bovee (b) (4)	17 Feb 2021 23:21:19

US3732094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:56

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:55:56
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '11:54'	Gordon Bovee (b) (4)	17 Feb 2021 23:21:19

US3732094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:55:56
User entered '14 Jan 2021 11:54'	System	17 Feb 2021 23:21:19

US3732094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:29:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:55:56
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	15 Mar 2021 19:04:56

US3732094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:29:56

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:55:56
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
User entered '14 Jan 2021'	Gordon Bovee (b) (4)	15 Mar 2021 19:04:56

US3732094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:29:56

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:55:56
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
User entered '11:49'	Gordon Bovee (b) (4)	15 Mar 2021 19:04:56

US3732094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:29:56

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:55:56
User entered '14 Jan 2021 11:49'	System	15 Mar 2021 19:04:56

US3732094

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:29:56

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:31:52
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:21
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:21:15

US3732094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:56

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:00:52
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:32
User entered	System	20 Jan 2021 14:45:14
'USA-US102-2021-mRNA-1273-P301000003'		
User entered 'New'	(b) (4), (b) (6)	20 Jan 2021 14:45:14

US3732094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:56

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:27:35
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Supraventricular tachycardia, LLT: Supraventricular tachycardia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Jan 2021 20:34:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Jan 2021 20:34:09
Data point term sent to Coder	System	19 Jan 2021 20:33:25
User entered 'SUPRAVENTRICULAR TACHYCARDIA'	(b) (4), (b) (6)	19 Jan 2021 20:32:59

US3732094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:27:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 20:32:59

US3732094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:27:45
User entered 'No (N)'	(b) (4), (b) (6)	19 Jan 2021 20:32:59

US3732094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:27:47
User entered 'No (N)'	(b) (4), (b) (6)	19 Jan 2021 20:32:59

US3732094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:27:51
User entered '24 Dec 2020'	(b) (4), (b) (6)	19 Jan 2021 20:32:59

US3732094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:56

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:27:52
User entered empty.	(b) (4), (b) (6)	19 Jan 2021 20:32:59

US3732094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Jan 2021 20:32:59

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 21:11:24
DataPoint Un-verified.	He (Helen) Pu (b) (4)	09 Apr 2021 21:41:13
	(b) (4)	
User entered 'No (N)' reason for change: New Information	He (Helen) Pu (b) (4)	09 Apr 2021 21:41:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:55
	(b) (4), (b) (6)	
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Jan 2021 20:33:56
	(b) (4), (b) (6)	
User entered 'No (N)'	(b) (4), (b) (6)	19 Jan 2021 20:32:59

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User closed query 'Query: event outcome was reported as resolved, with end date of 25 Dec 2020; however, answered query states that the event was still ongoing. can you confirm that the event did resolve, or if not, please update end date/outcome. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:00:15
Query 'Query: event outcome was reported as resolved, with end date of 25 Dec 2020; however, answered query states that the event was still ongoing. can you confirm that the event did resolve, or if not, please update end date/outcome. ' answered with 'recovered/resolved' (Site from Safety).	Gordon Bovee (b) (4) (b) (4)	22 Apr 2021 19:00:47
User opened query 'Query: event outcome was reported as resolved, with end date of 25 Dec 2020; however, answered query states that the event was still ongoing. can you confirm that the event did resolve, or if not, please update end date/outcome. ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 12:53:45
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:12:41
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	09 Apr 2021 21:41:51
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	09 Apr 2021 21:41:51
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	09 Apr 2021 21:41:13
DataPoint Un-verified.	He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 21:41:13
User entered '25 Dec 2020' reason for change: New Information	He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 21:41:13
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:56
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	19 Jan 2021 20:33:56

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	19 Jan 2021 20:32:59
User entered empty.	(b) (4), (b) (6)	19 Jan 2021 20:32:59

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:27:58
User entered empty.	(b) (4), (b) (6)	19 Jan 2021 20:32:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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. ' canceled (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 00:02:13
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)	28 Jan 2021 19:59:44
User entered empty.	System	19 Jan 2021 20:32:59

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Severity

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:14:30
User closed query 'Per AE Log, "Severity = Grade 3/Severe". Please re-confirm with Source and Update Severity.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 21:10:03
Query 'Per AE Log, "Severity = Grade 3/Severe". Please re-confirm with Source and Update Severity.' answered with 'updated' (Site from CRA).	He (Helen) Pu (b) (4) (b) (4)	05 Apr 2021 22:56:35
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	He (Helen) Pu (b) (4) (b) (4)	05 Apr 2021 22:56:26
User opened query 'Per AE Log, "Severity = Grade 3/Severe". Please re-confirm with Source and Update Severity.' (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 23:28:36
Query 'PV Query: Since the subject was hospitalized for the event of supraventricular tachycardia, appropriate CTCAE grade should be grade 3 instead of grade 1/grade 2. Please update the event severity as such. If the severity is to remain grade 1/grade 2, please clarify/explain.' canceled (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 19:04:06
User opened query 'PV Query: Since the subject was hospitalized for the event of supraventricular tachycardia, appropriate CTCAE grade should be grade 3 instead of grade 1/grade 2. Please update the event severity as such. If the severity is to remain grade 1/grade 2, please clarify/explain.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 19:57:54
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	19 Jan 2021 20:32:59

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Folder: Adverse Events

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:28:38
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	19 Jan 2021 20:33:56
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	19 Jan 2021 20:32:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 20:32:59

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:28:45
User entered '0'	(b) (4), (b) (6)	19 Jan 2021 20:32:59

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Folder: Adverse Events

Form: Adverse Events (1)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:28:49
User entered '0'	(b) (4), (b) (6)	19 Jan 2021 20:32:59

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Folder: Adverse Events

Form: Adverse Events (1)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:28:51
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	19 Jan 2021 20:33:56
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	19 Jan 2021 20:33:56
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Jan 2021 20:33:56
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	19 Jan 2021 20:32:59
User entered '0'	(b) (4), (b) (6)	19 Jan 2021 20:32:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:56

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:29:01
User entered '24 Dec 2020'	(b) (4), (b) (6)	19 Jan 2021 20:32:59

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:29:03
User entered '25 Dec 2020'	(b) (4), (b) (6)	19 Jan 2021 20:32:59

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:29:04
User entered 'No (N)' reason for change: Data Entry Error	Gordon Bovee (b) (4) (b) (4)	23 Mar 2021 17:20:48
User closed query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	23 Mar 2021 17:20:08
Query 'Admitted to ICU?' is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		23 Mar 2021 17:20:08
User entered 'Yes (Y)' reason for change: New Information	Gordon Bovee (b) (4) (b) (4)	23 Mar 2021 17:20:08
User opened query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	19 Jan 2021 20:32:59
User entered 'Unknown (UNK)'	(b) (4), (b) (6)	19 Jan 2021 20:32:59

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Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:29:06
User closed query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	23 Mar 2021 17:20:48
Query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' answered by data change (Site from System).	System	23 Mar 2021 17:20:48
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	23 Mar 2021 17:20:08
User entered empty.	(b) (4), (b) (6)	19 Jan 2021 20:32:59

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:29:08
User entered '0'	(b) (4), (b) (6)	19 Jan 2021 20:32:59

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:29:09
User entered '0'	(b) (4), (b) (6)	19 Jan 2021 20:32:59

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:29:11
User entered '0'	(b) (4), (b) (6)	19 Jan 2021 20:32:59

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:29:12
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	19 Jan 2021 20:32:59

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:29:14
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	19 Jan 2021 20:32:59

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:29:16
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	19 Jan 2021 20:32:59

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 23:29:19
User entered '0'	(b) (4), (b) (6)	19 Jan 2021 20:32:59

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:22:43
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:29:22
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'conmed line 4 metoprolol is recorded for this AE.' (Site from DM).	Makenna Orel (b) (4) (b) (4)	23 Mar 2021 18:24:23
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 08:07:37
User entered 'I'	(b) (4), (b) (6)	19 Jan 2021 20:32:59

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:29:25
User entered '0'	(b) (4), (b) (6)	19 Jan 2021 20:32:59

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:12:55
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 14:10:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 21:41:51
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' answered with 'still ongoing' (Site from Safety).	Gordon Bovee (b) (4) (b) (4)	09 Apr 2021 19:42:21
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 20:00:43
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	19 Jan 2021 20:32:59

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:29:30
User entered empty.	(b) (4), (b) (6)	19 Jan 2021 20:32:59

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User closed query 'PV Query: could the reports for the chest x-ray, head and neck CTA, echocardiogram, and ECGs be provided? ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 13:05:07
User closed query 'PV Query: could you confirm subject's use of Norvasc, aspirin, Lunesta, and Desyrel as concomitant products and add to con med log? ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 13:04:59
User closed query 'PV Query: could you confirm subject's dose of simvastatin? per medical records is 40 mg/day ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 13:04:53
User closed query 'PV Query: thank you for providing ED records; as such, the dates were redacted. would copies of ED records without dates redacted be able to be provided to _Moderna@iqvia.com or fax to 866.599.1342? thank you. ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 13:04:47
Query 'PV Query: could the reports for the chest x-ray, head and neck CTA, echocardiogram, and ECGs be provided? ' answered with 'Medical records without dates redacted were sent via email to Moderna@iqvia.com. Please review.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 21:59:47
Query 'PV Query: thank you for providing ED records; as such, the dates were redacted. would copies of ED records without dates redacted be able to be provided to _Moderna@iqvia.com or fax to 866.599.1342? thank you. ' answered with 'Medical records without dates redacted were sent via email to Moderna@iqvia.com. Please review.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 21:59:44
Query 'PV Query: could you confirm subject's use of Norvasc, aspirin, Lunesta, and Desyrel as concomitant products and add to con med log? ' answered with 'Confirmed uses of the following medications with subject. Updated in con meds and updated medical history as necessary, per subject.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 18:06:45

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: could you confirm subject's dose of simvastatin? per medical records is 40 mg/day ' answered with 'Confirmed per medical records, simvastatin dosage is 40 mg/day. Updated in con meds.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 17:37:31
User opened query 'PV Query: could the reports for the chest x-ray, head and neck CTA, echocardiogram, and ECGs be provided? ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 12:53:33
User opened query 'PV Query: could you confirm subject's use of Norvasc, aspirin, Lunesta, and Desyrel as concomitant products and add to con med log? ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 12:53:26
User opened query 'PV Query: could you confirm subject's dose of simvastatin? per medical records is 40 mg/day ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 12:53:19
User opened query 'PV Query: thank you for providing ED records; as such, the dates were redacted. would copies of ED records without dates redacted be able to be provided to _Moderna@iqvia.com or fax to 866.599.1342? thank you. ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 12:52:56
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:14:14
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 14:10:57
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 14:10:50

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[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. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 14:10:45
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 14:10:38
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'updated' (Site from Safety).	He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 22:35:38
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' answered with 'updated - please see sent email for redacted lab results' (Site from Safety).	He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 22:35:33
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so' answered with 'updated' (Site from Safety).	He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 22:35:22
DataPoint Un-verified.	He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 22:35:16

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT REPORTS OVERNIGHT HOSPITAL STAY FROM 24 DEC 2020 - 25 DEC 2020 TO RULE OUT CARDIAC ISSUE AS HE WENT TO THE ER FOR PALPITATIONS AND MILD CHEST TIGHTNESS ON 24 DEC 2020. DIAGNOSED WITH SUPRAVENTRICULAR TACHYCARDIA (RATE UNKNOWN). 09Apr2021 MR narrative update - negative COVID-19 mid-turbinate swab on 24Dec2020. Please see sent email for redacted ED notes for labs. Diagnostic tests done include chest x-ray (24Dec2020), head and neck CTA (24Dec2020), echocardiogram (25Dec2020), and multiple ECGs (24-25Dec2020). Chest x-ray normal. Head and neck CTA showed normal findings except for a 3.6 cm left thyroid cyst causing deviation of the left carotid artery and jugular vein. Echo findings normal. The 4 ECGs from 24-25Dec2020 indicated either normal sinus rhythm or sinus bradycardia. Treatment at hospital consisted of a 5 mg metoprolol IV push with daily 12.5 mg BID oral metoprolol following discharge.' reason for change: New Information	He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 22:35:16
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'updated - note no discharge summary, just ED note. Patient spent overnight in ED (observation?)' (Site from Safety). DataPoint Verified.	He (Helen) Pu (b) (4) (b) (4) (b) (4), (b) (6)	09 Apr 2021 21:38:29 23 Mar 2021 23:29:40
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	28 Jan 2021 20:02:01

US3732094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:56

[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)	28 Jan 2021 20:01:21
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 20:00:30
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 19:56:33
User entered 'SUBJECT REPORTS OVERNIGHT HOSPITAL STAY FROM 24 DEC 2020 - 25 DEC 2020 TO RULE OUT CARDIAC ISSUE AS HE WENT TO THE ER FOR PALPITATIONS AND MILD CHEST TIGHTNESS ON 24 DEC 2020. DIAGNOSED WITH SUPRAVENTRICULAR TACHYCARDIA (RATE UNKNOWN).' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Jan 2021 20:34:19
User entered 'SUBJECT REPORTS OVERNIGHT HOSPITAL STAY FROM 24 DEC 2020 - 25 DEC 2020 TO RULE OUT CARDIAC ISSUE AS HE WENT TO THE ER FOR PALPITATIONS AND MILD CHET TIGHTNESS ON 24 DEC 2020. DIAGNOSED WITH SUPRAVENTRICULAR TACHYCARDIA (RATE UNKNOWN).' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Jan 2021 20:33:56

US3732094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:56

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT REPORTS OVERNIGHT HOSPITAL STAY FROM 24 DEC 2020 - 25 DEC 2020 TO RULE OUT CARDIAC ISSUE AS HE WENT TO THE ER FOR PALPITATIONS AND MILD CHEST TIGHTNESS ON 24 DEC 2020. DIAGNOSED WITH SUPRAVENTRICULAR TACHYCARDIA (RATE UNKNOWN).'	(b) (4), (b) (6)	19 Jan 2021 20:32:59

US3732094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:56

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Jan 2021 20:32:59

US3732094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Jan 2021 20:32:59

US3732094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:56

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Mar 2021 17:20:48
User entered '1'	System	23 Mar 2021 17:20:08
User entered '0'	System	19 Jan 2021 20:32:59

US3732094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47

US3732094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Endocrine neoplasms malignant and unspecified, HLT: Thyroid neoplasms malignant, PT: Papillary thyroid cancer, LLT: Papillary thyroid cancer - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	27 Apr 2021 00:04:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	27 Apr 2021 00:04:52
Data point term sent to Coder	System	26 Apr 2021 20:49:07
DataPoint Un-verified.	He (Helen) Pu (b) (4)	26 Apr 2021 20:49:05
Coding entries removed.	(b) (4) He (Helen) Pu (b) (4)	26 Apr 2021 20:49:05
User entered 'RIGHT SIDE papillary THYROID CANCER' reason for change: New Information	(b) (4) He (Helen) Pu (b) (4)	26 Apr 2021 20:49:05
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:30:05
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Endocrine neoplasms malignant and unspecified, HLT: Thyroid neoplasms malignant, PT: Thyroid cancer, LLT: Thyroid cancer - version MedDRA\23.0.	Coder Import (b) (4)	16 Mar 2021 01:11:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	16 Mar 2021 01:11:56
Data point term sent to Coder	System	15 Mar 2021 19:19:04
User entered 'right side thyroid cancer'	Gordon Bovee (b) (4)	15 Mar 2021 19:18:29
	(b) (4)	

US3732094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:30:06
User entered 'Yes (Y)'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:18:29

US3732094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:30:08
User entered 'No (N)'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:18:29

US3732094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:30:10
User entered 'No (N)'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:18:29

US3732094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:30:13
User entered '15 Jan 2021'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:18:29

US3732094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:30:14
User entered empty.	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:18:29

US3732094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47
User entered empty.	System	15 Mar 2021 19:18:29

US3732094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:15:24
DataPoint Un-verified.	Sylvia Lindholm (b) (4)	15 Apr 2021 00:01:01
User entered 'No (N)' reason for change: New Information	Sylvia Lindholm (b) (4)	15 Apr 2021 00:01:01
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:30:16
User entered 'Yes (Y)'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:18:29

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Un-verified.	(b) (4)	
	He (Helen) Pu (b) (4)	26 Apr 2021 20:49:05
	(b) (4)	
User entered '26 Feb 2021' reason for change: Data Entry Error	He (Helen) Pu (b) (4)	26 Apr 2021 20:49:05
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 21:14:55
DataPoint Un-verified.	Sylvia Lindholm (b) (4)	15 Apr 2021 00:01:01
User entered '25 Feb 2021' reason for change: New Information	Sylvia Lindholm (b) (4)	15 Apr 2021 00:01:01
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:30:19
User entered empty.	Gordon Bovee (b) (4)	15 Mar 2021 19:18:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:30:22
User entered empty.	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:18:29

US3732094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47
User entered empty.	System	15 Mar 2021 19:18:29

US3732094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:30:26
User entered 'Grade 3/Severe (Grade 3/Severe)'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:18:29

US3732094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47
User closed query 'Per MM: Please confirm this event did not meet serious criteria and update, as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 12:52:38
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
Query 'Per MM: Please confirm this event did not meet serious criteria and update, as appropriate.' answered with 'confirmed correct as is by PI after review' (Site from DM).	(b) (4) He (Helen) Pu (b) (4)	28 Apr 2021 19:05:28
User opened query 'Per MM: Please confirm this event did not meet serious criteria and update, as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Apr 2021 14:23:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:30:30
User entered 'No (N)'	Gordon Bovee (b) (4)	15 Mar 2021 19:18:29

US3732094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:30:33
User entered '0'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:18:29

US3732094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:30:35
User entered '0'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:18:29

US3732094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:30:36
User entered '0'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:18:29

US3732094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:30:38
User entered empty.	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:18:29

US3732094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:30:40
User entered empty.	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:18:29

US3732094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:30:42
User entered empty.	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:18:29

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:30:43
User entered empty.	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:18:29

US3732094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:30:45
User entered '0'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:18:29

US3732094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:30:46
User entered '0'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:18:29

US3732094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:30:48
User entered '0'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:18:29

US3732094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:30:50
User entered 'Not Related (NOT RELATED)'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:18:29

US3732094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:30:53
User entered 'Not Applicable (NOT APPLICABLE)'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:18:29

US3732094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:30:55
User entered 'Not Applicable (NOT APPLICABLE)'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:18:29

US3732094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:30:57
User entered '0'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:18:29

US3732094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:30:59
User entered 'l'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:18:29

US3732094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:31:01
User entered 'I'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:18:29

US3732094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:15:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Sylvia Lindholm (b) (4)	15 Apr 2021 00:01:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	08 Apr 2021 04:01:00
Query 'Data is required. Please complete.' answered with 'open AE - as of 26Feb2021, "improving, well-controlled" per MR' (Site from System).	He (Helen) Pu (b) (4)	05 Apr 2021 23:00:36
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 19:18:29
User entered empty.	Gordon Bovee (b) (4)	15 Mar 2021 19:18:29

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:31:28
User entered empty.	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:18:29

US3732094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:31:29
User entered empty.	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:18:29

US3732094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47
User entered '0'	System	15 Mar 2021 19:18:29

US3732094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47
User entered 'I'	System	15 Mar 2021 19:18:29

US3732094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:56

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:54:47

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:29:56

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:31:52
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:32:08
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 02:24:08

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:56

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:33:01
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 02:27:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 02:27:09
Data point term sent to Coder User entered 'losartan'	System Lauren Arnett (b) (4)	21 Aug 2020 02:25:41 21 Aug 2020 02:24:56

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:56

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:33:01
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'No (N)'	Lauren Arnett (b) (4)	21 Aug 2020 02:24:56

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:56

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:33:01
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'hypertension'	Lauren Arnett (b) (4)	21 Aug 2020 02:24:56

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:56

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:33:01
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '50'	Lauren Arnett (b) (4)	21 Aug 2020 02:24:56

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:56

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:33:01
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'mg (mg)'	Lauren Arnett (b) (4)	21 Aug 2020 02:24:56

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:56

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:33:01
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Lauren Arnett (b) (4)	21 Aug 2020 02:24:56

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:56

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:33:01
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'once daily (QD)'	Lauren Arnett (b) (4)	21 Aug 2020 02:24:56

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:33:01
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Lauren Arnett (b) (4)	21 Aug 2020 02:24:56

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:56

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:33:01
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4)	21 Aug 2020 02:24:56

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:56

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:33:01
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Lauren Arnett (b) (4)	21 Aug 2020 02:24:56

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:33:01
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:37:33
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System).	Lauren Arnett (b) (4)	21 Aug 2020 02:25:11
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	21 Aug 2020 02:24:56
User entered 'un UNK 2015'	Lauren Arnett (b) (4)	21 Aug 2020 02:24:56

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:33:01
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	21 Aug 2020 02:24:56

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:33:01
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	21 Aug 2020 02:24:56

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:33:01
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Lauren Arnett (b) (4)	21 Aug 2020 02:24:56

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:33:01
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'No (N)'	Lauren Arnett (b) (4)	21 Aug 2020 02:24:56

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 02:24:56

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 02:24:56

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 02:24:56

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:46
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:33:50
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Aug 2020 23:03:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 23:03:16
Data point term sent to Coder	System	22 Aug 2020 23:03:00
User entered 'simvastatin'	Lauren Arnett (b) (4) (b) (4)	22 Aug 2020 23:02:27

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:46
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:33:52
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	22 Aug 2020 23:02:27

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:46
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:33:54
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'hypercholesterolemia'	(b) (4) Lauren Arnett (b) (4) (b) (4)	22 Aug 2020 23:02:27

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:46
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:33:56
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '20'	(b) (4) Lauren Arnett (b) (4) (b) (4)	22 Aug 2020 23:02:27

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:46
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:33:58
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'mg (mg)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	22 Aug 2020 23:02:27

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:46
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:34:00
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	(b) (4) Lauren Arnett (b) (4) (b) (4)	22 Aug 2020 23:02:27

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:46
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:34:02
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'once daily (QD)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	22 Aug 2020 23:02:27

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:46
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:34:03
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	(b) (4) Lauren Arnett (b) (4) (b) (4)	22 Aug 2020 23:02:27

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:46
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:34:06
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Oral (ORAL)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	22 Aug 2020 23:02:27

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:56

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:46
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:34:07
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	(b) (4) Lauren Arnett (b) (4) (b) (4)	22 Aug 2020 23:02:27

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:46
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:34:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'un UNK 2015'	(b) (4) Lauren Arnett (b) (4) (b) (4)	22 Aug 2020 23:02:27

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:46
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:34:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	(b) (4) Lauren Arnett (b) (4) (b) (4)	22 Aug 2020 23:02:27

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:46
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:37:55
Signature has been broken.	(b) (4), (b) (6)	23 Apr 2021 17:37:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 17:37:55
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:34:13
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
	(b) (4)	
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	22 Aug 2020 23:02:27
	(b) (4)	

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:46
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 17:37:55
Signature has been broken.	(b) (4), (b) (6)	23 Apr 2021 17:37:55
User entered '27 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 17:37:55
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:34:15
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	(b) (4)	
	Lauren Arnett (b) (4)	22 Aug 2020 23:02:27
	(b) (4)	

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:46
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:34:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	22 Aug 2020 23:02:27

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:46
User entered '1'	System	22 Aug 2020 23:02:27

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:46
User entered '1'	System	22 Aug 2020 23:02:27

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:46
User entered '804 (804)'	System	22 Aug 2020 23:02:27

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:56

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:34:25
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 17:07:38
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 17:07:38
Data point term sent to Coder	System	25 Sep 2020 16:44:59
User entered 'tylenol'	Lauren Arnett (b) (4)	25 Sep 2020 16:44:38

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:56

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:34:28
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'No (N)'	Lauren Arnett (b) (4)	25 Sep 2020 16:44:38

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:56

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:34:30
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'non-migraine headaches'	Lauren Arnett (b) (4)	25 Sep 2020 16:44:38

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:56

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:34:33
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '200'	Lauren Arnett (b) (4)	25 Sep 2020 16:44:38

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:56

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:34:35
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'mg (mg)'	Lauren Arnett (b) (4)	25 Sep 2020 16:44:38

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:56

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:34:37
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Lauren Arnett (b) (4)	25 Sep 2020 16:44:38

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:56

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:34:39
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'as needed (PRN)'	Lauren Arnett (b) (4)	25 Sep 2020 16:44:38

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:56

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:34:40
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Lauren Arnett (b) (4)	25 Sep 2020 16:44:38

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:56

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:34:42
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4)	25 Sep 2020 16:44:38

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:56

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:34:45
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Lauren Arnett (b) (4)	25 Sep 2020 16:44:38

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:34:47
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'un UNK 1990'	Lauren Arnett (b) (4)	25 Sep 2020 16:44:38

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:34:48
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '0'	Lauren Arnett (b) (4)	25 Sep 2020 16:44:38

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:34:50
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	25 Sep 2020 16:44:38

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:34:51
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered empty.	Lauren Arnett (b) (4)	25 Sep 2020 16:44:38

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:34:53
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered 'No (N)'	Lauren Arnett (b) (4)	25 Sep 2020 16:44:38

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 16:44:38

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 16:44:38

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 16:44:38

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:56

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:15
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 09:00:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 09:00:57
Data point term sent to Coder Coding entries removed.	System He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 21:42:54 09 Apr 2021 21:42:44
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	31 Mar 2021 22:59:50
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:35:00
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 19:21:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 19:21:50
Data point term sent to Coder User entered 'metoprolol'	System Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:21:06 15 Mar 2021 19:20:06

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:15
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:35:02
User entered 'No (N)'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:20:06

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:15
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:35:04
User entered 'supraventricular tachycardia'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:20:06

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:15
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:47:29
DataPoint Un-verified.	(b) (4)	
	He (Helen) Pu (b) (4)	09 Apr 2021 21:42:44
Signature has been broken.	(b) (4)	
	He (Helen) Pu (b) (4)	09 Apr 2021 21:42:44
User entered '5' reason for change: New Information	(b) (4)	
	He (Helen) Pu (b) (4)	09 Apr 2021 21:42:44
User signature succeeded.	(b) (4)	
	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 23:35:06
User entered '25'	(b) (4)	
	Gordon Bovee (b) (4)	15 Mar 2021 19:20:06
	(b) (4)	

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:15
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:35:09
User entered 'mg (mg)'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:20:06

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:15
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:35:10
User entered empty.	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:20:06

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:15
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:47:29
DataPoint Un-verified.	(b) (4)	
	He (Helen) Pu (b) (4)	09 Apr 2021 21:42:44
Signature has been broken.	(b) (4)	
	He (Helen) Pu (b) (4)	09 Apr 2021 21:42:44
User entered 'once (ONCE)' reason for change: New Information	(b) (4)	09 Apr 2021 21:42:44
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 23:35:12
User entered 'once daily (QD)'	Gordon Bovee (b) (4)	15 Mar 2021 19:20:06
	(b) (4)	

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:15
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:35:14
User entered empty.	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:20:06

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:15
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:47:29
DataPoint Un-verified.	(b) (4)	
	He (Helen) Pu (b) (4)	09 Apr 2021 21:42:44
Signature has been broken.	(b) (4)	
	He (Helen) Pu (b) (4)	09 Apr 2021 21:42:44
User entered 'Intravenous (INTRAVENOUS)'	(b) (4)	
reason for change: New Information	He (Helen) Pu (b) (4)	09 Apr 2021 21:42:44
User signature succeeded.	(b) (4)	
	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 23:35:15
User entered 'Oral (ORAL)'		
	Gordon Bovee (b) (4)	15 Mar 2021 19:20:06
	(b) (4)	

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:56

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:15
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:35:18
User entered empty.	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:20:06

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:15
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:35:20
User entered '24 Dec 2020'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:20:06

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:15
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:35:22
User entered '0'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:20:06

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:15
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:47:29
DataPoint Un-verified.	(b) (4)	
	He (Helen) Pu (b) (4)	09 Apr 2021 21:42:44
Signature has been broken.	(b) (4)	
	He (Helen) Pu (b) (4)	09 Apr 2021 21:42:44
User entered 'No (N)' reason for change: New Information	(b) (4)	
	He (Helen) Pu (b) (4)	09 Apr 2021 21:42:44
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 23:35:24
User entered 'Yes (Y)'		
	Gordon Bovee (b) (4)	15 Mar 2021 19:20:06
	(b) (4)	

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:15
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:47:29
DataPoint Un-verified.	(b) (4)	
	He (Helen) Pu (b) (4)	09 Apr 2021 21:42:44
Signature has been broken.	(b) (4)	
	He (Helen) Pu (b) (4)	09 Apr 2021 21:42:44
User entered '24 Dec 2020' reason for change: New Information	(b) (4)	
	He (Helen) Pu (b) (4)	09 Apr 2021 21:42:44
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 23:35:25
User entered empty.	Gordon Bovee (b) (4)	15 Mar 2021 19:20:06
	(b) (4)	

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:15
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:35:27
User entered 'No (N)'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:20:06

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:15
User entered empty.	System	09 Apr 2021 21:42:44
User entered '1'	System	15 Mar 2021 19:20:06

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:15
User entered empty.	System	09 Apr 2021 21:42:44
User entered '1'	System	15 Mar 2021 19:20:06

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:15
User entered empty.	System	09 Apr 2021 21:42:44
User entered '804 (804)'	System	15 Mar 2021 19:20:06

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:32
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:36:28
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LIOETHYRONINE SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 10:21:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 10:21:49
Data point term sent to Coder	System	15 Mar 2021 19:21:05
User entered 'liothyronine sodium'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:21:01

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:32
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:36:34
User entered 'No (N)'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:21:01

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:32
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:36:35
User entered 'thyroid cancer'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:21:01

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:32
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:36:39
User entered '25'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:21:01

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:32
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:36:43
User entered 'ug (ug)'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:21:01

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:32
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:36:45
User entered empty.	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:21:01

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:32
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:36:49
User entered 'once daily (QD)'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:21:01

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:32
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:36:52
User entered empty.	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:21:01

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:32
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:36:55
User entered 'Oral (ORAL)'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:21:01

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:56

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:32
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:36:59
User entered empty.	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:21:01

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:32
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:37:01
User entered '26 Feb 2021'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:21:01

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:32
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:37:02
User entered '0'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:21:01

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:32
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Un-verified.	(b) (4) Sylvia Lindholm (b) (4)	14 Apr 2021 22:51:18
Signature has been broken.	Sylvia Lindholm (b) (4)	14 Apr 2021 22:51:18
User entered 'No (N)' reason for change: New Information	Sylvia Lindholm (b) (4)	14 Apr 2021 22:51:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:37:04
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	15 Mar 2021 19:21:01

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:32
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
DataPoint Un-verified.	(b) (4) Sylvia Lindholm (b) (4)	14 Apr 2021 22:51:18
Signature has been broken.	Sylvia Lindholm (b) (4)	14 Apr 2021 22:51:18
User entered '13 Mar 2021' reason for change: New Information	Sylvia Lindholm (b) (4)	14 Apr 2021 22:51:18
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:37:06
User entered empty.	Gordon Bovee (b) (4)	15 Mar 2021 19:21:01

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:32
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:37:11
User entered 'No (N)'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:21:01

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:32
User entered '1'	System	15 Mar 2021 19:21:01

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:32
User entered '1'	System	15 Mar 2021 19:21:01

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:32
User entered '804 (804)'	System	15 Mar 2021 19:21:01

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:56

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:58:05
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Apr 2021 09:58:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 09:58:37
Data point term sent to Coder	System	05 Apr 2021 23:18:22
User entered 'levothyroxine'	He (Helen) Pu (b) (4) (b) (4)	05 Apr 2021 23:17:56

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:58:05
User entered 'Yes (Y)'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	05 Apr 2021 23:17:56

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:58:05
User entered 'thyroid hormone therapy status post total thyroidectomy'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	05 Apr 2021 23:17:56

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:58:05
User entered '137'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	05 Apr 2021 23:17:56

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:58:05
User entered 'ug (ug)'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	05 Apr 2021 23:17:56

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:58:05
User entered empty.	(b) (4) He (Helen) Pu (b) (4) (b) (4)	05 Apr 2021 23:17:56

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:58:05
User entered 'once daily (QD)'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	05 Apr 2021 23:17:56

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:58:05
User entered empty.	(b) (4) He (Helen) Pu (b) (4) (b) (4)	05 Apr 2021 23:17:56

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:58:05
User entered 'Oral (ORAL)'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	05 Apr 2021 23:17:56

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:58:05
User entered empty.	(b) (4) He (Helen) Pu (b) (4) (b) (4)	05 Apr 2021 23:17:56

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:58:05
User entered '13 Mar 2021'	(b) (4) He (Helen) Pu (b) (4)	05 Apr 2021 23:17:56
	(b) (4)	

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:58:05
User entered '0'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	05 Apr 2021 23:17:56

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:58:05
User entered 'Yes (Y)'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	05 Apr 2021 23:17:56

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:58:05
User entered empty.	(b) (4) He (Helen) Pu (b) (4) (b) (4)	05 Apr 2021 23:17:56

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:58:05
User entered 'No (N)'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	05 Apr 2021 23:17:56

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 23:17:56

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 23:17:56

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 23:17:56

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:47:29
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Apr 2021 21:44:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 21:44:41
Data point term sent to Coder	System	09 Apr 2021 21:43:56
User entered 'metoprolol'	He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 21:43:29

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:47:29
User entered 'Yes (Y)'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 21:43:29

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:47:29
User entered 'supraventricular tachycardia'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 21:43:29

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:47:29
User entered '12.5'	(b) (4) He (Helen) Pu (b) (4)	09 Apr 2021 21:43:29

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:47:29
User entered 'mg (mg)'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 21:43:29

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:47:29
	(b) (4)	
User entered empty.	He (Helen) Pu (b) (4)	09 Apr 2021 21:43:29
	(b) (4)	

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:47:29
User entered 'twice daily (BID)'	(b) (4) He (Helen) Pu (b) (4)	09 Apr 2021 21:43:29
	(b) (4)	

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:47:29
User entered empty.	(b) (4) He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 21:43:29

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:47:29
User entered 'Oral (ORAL)'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 21:43:29

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:47:29
User entered empty.	(b) (4) He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 21:43:29

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:47:29
User entered '25 Dec 2020'	(b) (4) He (Helen) Pu (b) (4)	09 Apr 2021 21:43:29

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:47:29
	(b) (4)	
User entered '0'	He (Helen) Pu (b) (4)	09 Apr 2021 21:43:29
	(b) (4)	

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:47:29
User entered 'Yes (Y)'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 21:43:29

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:47:29
	(b) (4)	
User entered empty.	He (Helen) Pu (b) (4)	09 Apr 2021 21:43:29
	(b) (4)	

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:47:29
User entered 'No (N)'	(b) (4) He (Helen) Pu (b) (4)	09 Apr 2021 21:43:29
	(b) (4)	

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	09 Apr 2021 21:43:29

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 21:43:29

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Apr 2021 21:43:29

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Apr 2021 17:40:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 17:40:57
Data point term sent to Coder	System	23 Apr 2021 17:40:03
User entered 'SIMVASTATIN'	(b) (4), (b) (6)	23 Apr 2021 17:39:03

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 17:39:03

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'HYPERCHOLESTEROLEMIA'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:39:03

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered '40'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:39:03

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:39:03

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:39:03

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:39:03

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:39:03

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Apr 2021 17:39:03

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:39:03

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:39:03

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:39:03

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:39:03

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:39:03

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:39:03

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 17:39:03

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 17:39:03

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 17:39:03

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE HYDROCHLORIDE, PRODUCTSYNONYM: DESYREL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Apr 2021 18:14:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 18:14:10
Data point term sent to Coder	System	23 Apr 2021 18:12:44
User entered 'DESYREL'	(b) (4), (b) (6)	23 Apr 2021 18:12:05

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 18:12:05

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'INSOMNIA'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:05

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered '100'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:05

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:05

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:05

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'every month (QM)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:05

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:05

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:05

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:05

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'UN UNK 2019'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:05

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:05

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:05

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:05

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:05

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 18:12:05

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 18:12:05

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '802 (802)'	System	23 Apr 2021 18:12:05

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:56

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:52
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE BESILATE, PRODUCTSYNONYM: NORVASC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Apr 2021 18:14:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 18:14:58
Data point term sent to Coder User entered 'NORVASC'	System (b) (4), (b) (6)	23 Apr 2021 18:13:45 23 Apr 2021 18:12:55

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:52
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:55

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:52
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'HYPERTENSION'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:55

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:52
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered '5'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:55

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:52
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:55

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:52
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:55

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:52
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:55

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:52
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:55

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:52
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:55

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:56

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:52
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:55

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:52
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'UN UNK 2011'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:55

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:52
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:55

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:52
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:55

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:52
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:55

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:52
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:12:55

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:52
User entered '1'	System	23 Apr 2021 18:12:55

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:52
User entered '1'	System	23 Apr 2021 18:12:55

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:52
User entered '804 (804)'	System	23 Apr 2021 18:12:55

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 18:16:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 18:16:08
Data point term sent to Coder	System	23 Apr 2021 18:14:46
User entered 'ASPIRIN'	(b) (4), (b) (6)	23 Apr 2021 18:13:52

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Apr 2021 18:13:52

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'GENERAL HEALTH'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:13:52

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered '81'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:13:52

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:13:52

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 18:13:52

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 18:14:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Apr 2021 18:14:01
User entered 'once daily (QD)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 18:14:01
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 18:13:52
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 18:13:52

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:13:52

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Apr 2021 18:13:52

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 18:13:52

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'UN UNK 2011'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:13:52

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:13:52

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Apr 2021 18:13:52

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 18:13:52

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 18:13:52

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 18:14:01
User entered empty.	System	23 Apr 2021 18:13:52

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 18:14:01
User entered empty.	System	23 Apr 2021 18:13:52

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 18:14:01
User entered empty.	System	23 Apr 2021 18:13:52

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:03
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ESZOPICLONE, PRODUCTSYNONYM: LUNESTA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Apr 2021 18:16:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 18:16:50
Data point term sent to Coder	System	23 Apr 2021 18:16:00
User entered 'LUNESTA'	(b) (4), (b) (6)	23 Apr 2021 18:14:50

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:03
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:50

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:03
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'INSOMNIA'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:50

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:03
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered '2'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:50

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:03
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:50

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:03
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:50

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:03
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:50

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:03
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:50

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:03
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:50

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:56

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:03
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:50

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:03
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'UN UNK 2019'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:50

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:03
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:50

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:03
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:50

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:03
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:50

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:03
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:14:50

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:03
User entered '1'	System	23 Apr 2021 18:14:50

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:03
User entered '1'	System	23 Apr 2021 18:14:50

US3732094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:41:03
User entered '804 (804)'	System	23 Apr 2021 18:14:50

US3732094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:29:56

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:31:52
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:40:10
User entered 'Yes (Y)'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:12:09

US3732094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:29:56

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:40:31
User entered '25 Feb 2021'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:12:54

US3732094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:29:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:40:32
User entered 'bilateral total thyroidectomy'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:12:54

US3732094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:29:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:40:35
User entered 'Adverse Event (AE)'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:12:54

US3732094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:29:56

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:40:37
User entered empty.	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 19:12:54

US3732094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:29:56

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:36:31
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered '24 Dec 2020'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 22:38:29

US3732094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:29:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:36:31
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'chest x-ray'	He (Helen) Pu (b) (4)	09 Apr 2021 22:38:29

US3732094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:29:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:36:31
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 22:38:29

US3732094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:29:56

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:36:31
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered empty.	(b) (4) He (Helen) Pu (b) (4)	09 Apr 2021 22:38:29

US3732094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:29:56

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:36:34
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered '25 Dec 2020'	He (Helen) Pu (b) (4)	09 Apr 2021 22:38:43

US3732094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:29:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:36:34
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'echocardiogram'	He (Helen) Pu (b) (4)	09 Apr 2021 22:38:43

US3732094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:29:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:36:34
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'Diagnostic (DIAGNOSTIC)'	He (Helen) Pu (b) (4)	09 Apr 2021 22:38:43

US3732094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:29:56

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:36:34
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered empty.	He (Helen) Pu (b) (4)	09 Apr 2021 22:38:43

US3732094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:29:56

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:36:38
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered '24 Dec 2020'	He (Helen) Pu (b) (4)	09 Apr 2021 22:38:57

US3732094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:29:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:36:38
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'head and neck CTA'	He (Helen) Pu (b) (4)	09 Apr 2021 22:38:57

US3732094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:29:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:36:38
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 22:38:57

US3732094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:29:56

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:36:38
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered empty.	(b) (4) He (Helen) Pu (b) (4)	09 Apr 2021 22:38:57

US3732094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:29:56

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:36:43
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered '24 Dec 2020'	He (Helen) Pu (b) (4)	09 Apr 2021 22:39:11

US3732094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:29:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:36:43
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'ECG'	He (Helen) Pu (b) (4)	09 Apr 2021 22:39:11

US3732094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:29:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:36:43
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 22:39:11

US3732094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:29:56

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:36:43
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered empty.	He (Helen) Pu (b) (4)	09 Apr 2021 22:39:11

US3732094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:29:56

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:36:49
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered '25 Dec 2020'	He (Helen) Pu (b) (4)	09 Apr 2021 22:39:21

US3732094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:29:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:36:49
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'ECG'	He (Helen) Pu (b) (4)	09 Apr 2021 22:39:21

US3732094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:29:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:36:49
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) He (Helen) Pu (b) (4)	09 Apr 2021 22:39:21

US3732094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:29:56

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:36:49
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered empty.	(b) (4) He (Helen) Pu (b) (4)	09 Apr 2021 22:39:21

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'USA-US102-2021-MRNA-1273-P301000003'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'Yes (Y)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'No (N)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'No (N)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'Yes (Y)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'No (N)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'No (N)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'No (N)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'Scott'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'Overcash'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered '5565 Grossmont Center Dr'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'La Mesa'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'CA'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered '91942'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'US'	System	20 Jan 2021 14:45:43

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 13:20:39
User entered '4'	System	12 Apr 2021 14:10:08
User entered '3'	System	06 Apr 2021 15:01:26
User entered '2'	System	24 Mar 2021 19:44:56
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
	(b) (4)	
User entered '1'	System	20 Jan 2021 14:45:43

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'USA-US102-2021-MRNA-1273-P301000003'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'Yes (Y)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'No (N)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'No (N)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'Yes (Y)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'No (N)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'No (N)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'No (N)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'Scott'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'Overcash'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered '5565 Grossmont Center Dr'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'La Mesa'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'CA'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered '91942'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'US'	System	20 Jan 2021 14:45:43

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 13:20:39
User entered '4'	System	12 Apr 2021 14:10:08
User entered '3'	System	06 Apr 2021 15:01:26
User entered '2'	System	24 Mar 2021 19:44:56
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
	(b) (4)	
User entered '1'	System	20 Jan 2021 14:45:43

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:29:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
User entered '20/Jan/2021 09:45'	(b) (4) System	20 Jan 2021 14:45:43

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:29:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'I'	(b) (4), (b) (6)	20 Jan 2021 14:45:43

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'USA-US102-2021-MRNA-1273-P301000003'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'Yes (Y)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'No (N)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'No (N)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'Yes (Y)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'No (N)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'No (N)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'No (N)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'Scott'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'Overcash'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered '5565 Grossmont Center Dr'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'La Mesa'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'CA'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered '91942'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'US'	System	20 Jan 2021 14:45:43

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 13:20:39
User entered '4'	System	12 Apr 2021 14:10:08
User entered '3'	System	06 Apr 2021 15:01:26
User entered '2'	System	24 Mar 2021 19:44:56
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
	(b) (4)	
User entered '1'	System	20 Jan 2021 14:45:43

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:29:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
User entered '24/Mar/2021 15:44'	(b) (4) System	24 Mar 2021 19:44:56

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:29:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:09:31
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:59:50
User entered 'I'	(b) (4), (b) (6)	24 Mar 2021 19:44:56

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'USA-US102-2021-MRNA-1273-P301000003'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'Yes (Y)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'No (N)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'No (N)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'Yes (Y)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'No (N)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'No (N)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'No (N)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'Scott'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'Overcash'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered '5565 Grossmont Center Dr'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'La Mesa'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'CA'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered '91942'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'US'	System	20 Jan 2021 14:45:43

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 13:20:39
User entered '4'	System	12 Apr 2021 14:10:08
User entered '3'	System	06 Apr 2021 15:01:26
User entered '2'	System	24 Mar 2021 19:44:56
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
	(b) (4)	
User entered '1'	System	20 Jan 2021 14:45:43

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:29:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:58:05
User entered '06/Apr/2021 11:01'	(b) (4) System	06 Apr 2021 15:01:26

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:29:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:09:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:58:05
User entered 'I'	(b) (4), (b) (6)	06 Apr 2021 15:01:26

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'USA-US102-2021-MRNA-1273-P301000003'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'Yes (Y)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'No (N)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'No (N)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'Yes (Y)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'No (N)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'No (N)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'No (N)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'Scott'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'Overcash'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered '5565 Grossmont Center Dr'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'La Mesa'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'CA'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered '91942'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'US'	System	20 Jan 2021 14:45:43

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 13:20:39
User entered '4'	System	12 Apr 2021 14:10:08
User entered '3'	System	06 Apr 2021 15:01:26
User entered '2'	System	24 Mar 2021 19:44:56
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
	(b) (4)	
User entered '1'	System	20 Jan 2021 14:45:43

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:29:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered '12/Apr/2021 14:10'	(b) (4) System	12 Apr 2021 14:10:08

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:29:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:10:08

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'USA-US102-2021-MRNA-1273-P301000003'	System	20 Jan 2021 14:45:14

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Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'Yes (Y)'	System	20 Jan 2021 14:45:14

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Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'No (N)'	System	20 Jan 2021 14:45:14

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Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'No (N)'	System	20 Jan 2021 14:45:14

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Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'Yes (Y)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'No (N)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'No (N)'	System	20 Jan 2021 14:45:14

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Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'No (N)'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'Scott'	System	20 Jan 2021 14:45:14

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Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'Overcash'	System	20 Jan 2021 14:45:14

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Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered '5565 Grossmont Center Dr'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'La Mesa'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'CA'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered '91942'	System	20 Jan 2021 14:45:14

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 23:27:09
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:21
User entered 'US'	System	20 Jan 2021 14:45:43

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 13:20:39
User entered '4'	System	12 Apr 2021 14:10:08
User entered '3'	System	06 Apr 2021 15:01:26
User entered '2'	System	24 Mar 2021 19:44:56
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:22:10
	(b) (4)	
User entered '1'	System	20 Jan 2021 14:45:43

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:29:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered '26/Apr/2021 06:20'	(b) (4) System	26 Apr 2021 13:20:39

US3732094

Folder: SAE USA-US102-2021-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:29:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:53
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 13:20:39