

US3792094 (Prod: Hope Research Institute LLC - Hunt - PPDS)

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:17:05

All time stamps listed in this document are displayed in GMT

US3792094

Form: Participant Creation

Generated On: 26 Nov 2020 11:17:05

[Participant ID](#)

US3792094

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

US3792094

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:17:05

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	09 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:17:05

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	66
Age Units	YEARS
Age (Derived)	66
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☒ Not Hispanic or Latino ☐ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:17:05

Date of Informed Consent (<i>dd MMM yyyy</i>)	9 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☐
	Amendment 3 ☐
	Amendment 4 ☒
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:17:05

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:17:05

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:17:05

Condition	DIABETIC NEUROPATHY
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:17:05

Condition	DIABETES MELLITUS, TYPE 2
Start date (dd MMM yyyy)	UN UNK 2001
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:17:05

Condition	HPERTENSION
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:17:05

Condition	BENIGN PROSTATIC HYPERPLASIA
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:17:05

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

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:17:05

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

US3792094

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:17:05

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:17:05

Condition	CARPAL TUNNEL SYNDROME, BILATERAL
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:17:05

Condition	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Start date (dd MMM yyyy)	UN UNK 1975
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1975
Start Year (derived)	1975
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:17:05

Condition	LEFT SHOULDER OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:17:05

Condition	RIGHT KIDNEY CYST
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒
	No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:17:05

Condition	GOUT
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒
	No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:17:05

Condition	OBESITY
Start date (dd MMM yyyy)	UN UNK 1972
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1972
Start Year (derived)	1972
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:17:05

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

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Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:17:05

Condition	CLOSED FRACTURE OF PHALANX OF LEFT 3RD TOE
Start date (dd MMM yyyy)	01 SEP 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:17:05

Condition	DIABETIC RETINOPATHY OF BOTH EYES
Start date (dd MMM yyyy)	18 JUN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:17:05

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	9 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	12:29 (24 HR)
Vital Signs Date and Time (derived)	9 OCT 2020 12:29
Height (<i>xxx.x</i>)	68.5 in
Weight (<i>xxx.x</i>)	330.0 lb
BMI (<i>xxx.x</i>)	49.54989 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:17:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 OCT 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

Generated On: 26 Nov 2020 11:17:05

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

WARES VENDOR AT (b) (6)

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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

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Folder: Screening

Form: Risk of Exposure

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Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	True
Specify	MOBILE HOME

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:17:05

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	9 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:17:05

What was the date of randomization? (dd MMM yyyy) 09 OCT 2020

What was the participant's randomization number? 191513

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:17:05

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:17:05

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	9 OCT 2020
Time of assessment (00:00-23:59)	12:29 (24 HR)
Vital Signs Date and Time (derived)	9 OCT 2020 12:29
Temperature (xxx.x)	97.6 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:17:05

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	9 OCT 2020
Time of assessment (00:00-23:59)	13:37 (24 HR)
Vital Signs Date and Time (derived)	9 OCT 2020 13:37
Temperature (xxx.x)	98.1 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	167 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: Physical Examination

Generated On: 26 Nov 2020 11:17:05

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

Generated On: 26 Nov 2020 11:17:05

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) 9 OCT 2020

What was the treatment time? (00:00-23:59) 13:08 (24 HR)

Treatment Date and Time (derived) 9 OCT 2020 13:08

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:17:05

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	9 OCT 2020
Collection time (<i>00:00-23:59</i>)	12:33 (24 HR)
Collection date and time (derived)	9 OCT 2020 12:33

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:17:05

Collection date (dd MMM yyyy)			9 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:38	9 OCT 2020 12:38
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:17:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

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 98.1 °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):

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

To **PREVENT** pain or fever from occurring True

PC Time Stamp 09 OCT 2020 13:48

PC Open Date & Time 09 OCT 2020 13:28

PC Close Date & Time 09 OCT 2020 15:58

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

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 96.8 °F

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

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

PC Time Stamp	09 OCT 2020 16:56
PC Open Date & Time	09 OCT 2020 16:53
PC Close Date & Time	10 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes ☒
	No ☐
Please record your TEMPERATURE in °F	97.5 °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	10 OCT 2020 12:02
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 OCT 2020 16:02

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 OCT 2020 12:29

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:17:05

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

95.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp 13 OCT 2020 13:05

PC Open Date & Time 13 OCT 2020 12:00

PC Close Date & Time 14 OCT 2020 11:59

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

14 OCT 2020 12:35

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:17:05

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp 15 OCT 2020 17:01

PC Open Date & Time 15 OCT 2020 12:00

PC Close Date & Time 16 OCT 2020 11:59

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

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

09 OCT 2020 13:50

PC Open Date & Time

09 OCT 2020 13:28

PC Close Date & Time

09 OCT 2020 15:58

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 OCT 2020 16:56

PC Open Date & Time

09 OCT 2020 16:53

PC Close Date & Time

10 OCT 2020 11:59

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:17:05

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

10 OCT 2020 12:03

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:17:05

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

11 OCT 2020 16:03

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:17:05

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

12 OCT 2020 12:29

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:17:05

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

13 OCT 2020 13:05

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:17:05

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

14 OCT 2020 12:36

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:17:05

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

15 OCT 2020 17:01

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

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 ☐

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

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

No ☒

Yes ☐

PC Time stamp	09 OCT 2020 13:51
PC Open Date & Time	09 OCT 2020 13:28
PC Close Date & Time	09 OCT 2020 15:58

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

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 ☐

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

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

No ☒

Yes ☐

PC Time stamp	09 OCT 2020 16:57
PC Open Date & Time	09 OCT 2020 16:53
PC Close Date & Time	10 OCT 2020 11:59

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:17:05

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 ☒

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:17:05

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 ☒

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:17:05

Yes ☐	
PC Time stamp	11 OCT 2020 16:03
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:17:05

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 ☒

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:17:05

Yes ☐	
PC Time stamp	12 OCT 2020 12:30
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:17:05

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 ☒

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:17:05

Yes ☐	
PC Time stamp	13 OCT 2020 13:06
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:17:05

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 ☒

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:17:05

Yes ☐	
PC Time stamp	14 OCT 2020 12:37
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:17:05

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 ☒

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:17:05

Yes ☐	
PC Time stamp	15 OCT 2020 17:02
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3792094

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:17:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3792094

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:17:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792094

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:17:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3792094

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:17:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792094

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:17:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3792094

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:17:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792094

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:17:05

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	6 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:17:05

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	6 NOV 2020
Time of assessment (00:00-23:59)	11:39 (24 HR)
Vital Signs Date and Time (derived)	6 NOV 2020 11:39
Temperature (xxx.x)	98.2 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:17:05

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	6 NOV 2020
Time of assessment (00:00-23:59)	13:09 (24 HR)
Vital Signs Date and Time (derived)	6 NOV 2020 13:09
Temperature (xxx.x)	98.2 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3792094

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:17:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 NOV 2020

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

US3792094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:17:05

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)	6 NOV 2020
What was the treatment time? (00:00-23:59)	12:19 (24 HR)
Treatment Date and Time (derived)	6 NOV 2020 12:19
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

US3792094

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:17:05

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

6 NOV 2020

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

11:43 (24 HR)

Collection date and time (derived)

6 NOV 2020 11:43

US3792094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:17:05

Collection date (dd MMM yyyy)			6 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:50	6 NOV 2020 11:50
Nasopharyngeal Swab 2	No		

US3792094

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:17:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

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

98.2 °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

06 NOV 2020 13:13

PC Open Date & Time

06 NOV 2020 12:39

PC Close Date & Time

06 NOV 2020 15:09

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

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 95.4 °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	06 NOV 2020 18:10
PC Open Date & Time	06 NOV 2020 16:04
PC Close Date & Time	07 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:17:05

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 NOV 2020 21:09

PC Open Date & Time

07 NOV 2020 12:00

PC Close Date & Time

08 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:17:05

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

08 NOV 2020 19:55

PC Open Date & Time

08 NOV 2020 12:00

PC Close Date & Time

09 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 NOV 2020 23:50

PC Open Date & Time

09 NOV 2020 12:00

PC Close Date & Time

10 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 NOV 2020 23:57

PC Open Date & Time

10 NOV 2020 12:00

PC Close Date & Time

11 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:17:05

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

98.2 °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

11 NOV 2020 21:00

PC Open Date & Time

11 NOV 2020 12:00

PC Close Date & Time

12 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:17:05

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

95.4 °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 12 NOV 2020 19:39

PC Open Date & Time 12 NOV 2020 12:00

PC Close Date & Time 13 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

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

06 NOV 2020 13:13

PC Open Date & Time

06 NOV 2020 12:39

PC Close Date & Time

06 NOV 2020 15:09

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

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

06 NOV 2020 18:11

PC Open Date & Time

06 NOV 2020 16:04

PC Close Date & Time

07 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:17:05

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

07 NOV 2020 21:10

PC Open Date & Time

07 NOV 2020 12:00

PC Close Date & Time

08 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:17:05

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

08 NOV 2020 19:56

PC Open Date & Time

08 NOV 2020 12:00

PC Close Date & Time

09 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:17:05

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

09 NOV 2020 23:50

PC Open Date & Time

09 NOV 2020 12:00

PC Close Date & Time

10 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:17:05

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

10 NOV 2020 23:58

PC Open Date & Time

10 NOV 2020 12:00

PC Close Date & Time

11 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:17:05

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

11 NOV 2020 21:00

PC Open Date & Time

11 NOV 2020 12:00

PC Close Date & Time

12 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:17:05

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

12 NOV 2020 19:39

PC Open Date & Time

12 NOV 2020 12:00

PC Close Date & Time

13 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

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 ☐

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

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

No ☒

Yes ☐

PC Time stamp	06 NOV 2020 13:14
PC Open Date & Time	06 NOV 2020 12:39
PC Close Date & Time	06 NOV 2020 15:09

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

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 ☐

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

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

No ☒

Yes ☐

PC Time stamp	06 NOV 2020 18:12
PC Open Date & Time	06 NOV 2020 16:04
PC Close Date & Time	07 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:17:05

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 ☒

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:17:05

Yes ☐	
PC Time stamp	07 NOV 2020 21:11
PC Open Date & Time	07 NOV 2020 12:00
PC Close Date & Time	08 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:17:05

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 ☒

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:17:05

Yes ☐	
PC Time stamp	08 NOV 2020 19:56
PC Open Date & Time	08 NOV 2020 12:00
PC Close Date & Time	09 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:17:05

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 ☒

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:17:05

Yes ☐	
PC Time stamp	09 NOV 2020 23:50
PC Open Date & Time	09 NOV 2020 12:00
PC Close Date & Time	10 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:17:05

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 ☒

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:17:05

Yes ☐	
PC Time stamp	10 NOV 2020 23:58
PC Open Date & Time	10 NOV 2020 12:00
PC Close Date & Time	11 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:17:05

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 ☒

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:17:05

Yes ☐	
PC Time stamp	11 NOV 2020 21:01
PC Open Date & Time	11 NOV 2020 12:00
PC Close Date & Time	12 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:17:05

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 ☒

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:17:05

Yes ☐	
PC Time stamp	12 NOV 2020 19:40
PC Open Date & Time	12 NOV 2020 12:00
PC Close Date & Time	13 NOV 2020 11:59

US3792094

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:17:05

Was Contact Attempted?

Yes ☒

No ☐

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

13 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3792094

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:17:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792094

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:17:05

Was Contact Attempted?

Yes ☒

No ☐

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

20 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3792094

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:17:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792094

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:17:05

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2020 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

17 DEC 2020 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

24 DEC 2020 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

31 DEC 2020 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JAN 2021 00:01

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14 JAN 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

DAY 103

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2021 00:01

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28 JAN 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JAN 2021 00:01

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04 FEB 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2021 00:01

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11 FEB 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 FEB 2021 00:01

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18 FEB 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

DAY 145

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAR 2021 00:01

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18 MAR 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

DAY 166

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

[Patient Cloud Close Date & Time](#)

22 APR 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

DAY 208

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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 ☐

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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 ☐

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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 ☐

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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 ☐

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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°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 ☐

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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 ☐

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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 ☐

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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 ☐

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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 ☐

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

DAY 460

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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 ☐

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

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03 FEB 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

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10 FEB 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

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13 FEB 2022 00:01

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17 FEB 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

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24 FEB 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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 ☐

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

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03 MAR 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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 ☐

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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°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 ☐

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

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24 MAR 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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 ☐

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

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31 MAR 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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 ☐

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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 ☐

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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 ☐

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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 ☐

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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 ☐

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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 ☐

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

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09 JUN 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

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16 JUN 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

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30 JUN 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

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07 JUL 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

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28 JUL 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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 ☐

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

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04 AUG 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

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11 AUG 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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 ☐

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

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14 AUG 2022 00:01

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18 AUG 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

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25 AUG 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

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01 SEP 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

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04 SEP 2022 00:01

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08 SEP 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

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15 SEP 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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22 SEP 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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 ☐

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

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29 SEP 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

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02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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 ☐

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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 ☐

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

[Patient Cloud Close Date & Time](#)

17 NOV 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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 ☐

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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 ☐

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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 ☐

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

DAY 796

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2022 23:59

US3792094

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:17:05

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3792094

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Nov 2020 23:31:49

Generated On: 26 Nov 2020 11:17:05

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

AEID	USA-US057-2020-MRNA-1273-P30 1000001
Adverse event	ACUTE KIDNEY INJURY
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)	20 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	22 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	20 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	22 OCT 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	336 of 2163

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

SUB I NOTE: SPOKE WITH
PATIENT FOR DAY 15 SAFETY
FOLLOW UP PHONE CALL.
WOKE UP TUESDAY MORNING
10.20.20 AND HIS ENTIRE BODY
WAS SWOLLEN. WENT TO THE
HOSPITAL AND WAS
ADMITTED. RELEASED
YESTERDAY , (10/22/2020). HIS
KIDNEY FUNCTION WAS DOWN
TO 44%. WAS GIVEN LASIX,
WHICH HELPED.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	0

US3792094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

AEID	
Adverse event	PULMONARY CONGESTION
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)	20 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	22 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	339 of 2163

US3792094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

AEID	
Adverse event	ELEVATED BLOOD GLUCOSE
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)	20 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

v6.020 DTW (1102)

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US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

AEID	
Adverse event	RIGHT KIDNEY CYST
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)	20 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:17:05

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

Yes ☒

No ☐

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

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:17:05

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:17:05

Name of Medication	JARDIANCE
Prophylaxis	Yes ☐ No ☒
Indication	DIABETES MELLITUS, TYPE 2
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 ☐ Intramuscular ☐

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:17:05

Name of Medication	CARVEDILOL
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
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 ☐ Intramuscular ☐

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:17:05

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:17:05

Name of Medication	TAMSULOSIN
Prophylaxis	Yes ☐ No ☒
Indication	BENIGN PROSTATIC HYPERPLASIA
Dose per administration	0.4
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 ☐

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:17:05

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:17:05

Name of Medication	DULOXETINE
Prophylaxis	Yes ☐ No ☒
Indication	DIABETIC NEUROPATHY
Dose per administration	60
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:17:05

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:17:05

Name of Medication	ASPIRIN
Prophylaxis	Yes ☒ No ☐
Indication	CARDIAC PROPHYAXIS
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 ☐ Intramuscular ☐

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:17:05

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:17:05

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify	
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Ongoing?	Yes ☐
	No ☒
If not Ongoing, End date (dd MMM yyyy)	20 OCT 2020
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:17:05

Name of Medication	PANTOPRAZOLE
Prophylaxis	Yes ☐ No ☒
Indication	ACID REFLUX
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 ☐ Intramuscular ☐

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:17:05

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2008
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:17:05

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:17:05

Name of Medication	LASIX
Prophylaxis	Yes ☐ No ☒
Indication	ACUTE KIDNEY INJURY
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 ☐ Intramuscular ☐

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:17:05

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☒
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	20 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ☒
If not Ongoing, End date (dd MMM yyyy) 22 OCT 2020	
Was this medication taken for solicited event?	Yes ☐ No ☒
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☒

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:17:05

Name of Medication LASIX

Prophylaxis Yes ☐
No ☒

Indication ACUTE KIDNEY INJURY

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 ☐
Intramuscular ☐

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:17:05

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	22 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)	05 NOV 2020	
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	803 ☐
	804 ☒	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:17:05

Name of Medication	INSULIN GLARGINE
Prophylaxis	Yes ☐ No ☒
Indication	DIABETES MELLITUS TYPE 2
Dose per administration	45
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☒ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☒ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:17:05

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	28 OCT 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:17:05

Name of Medication ACETAMINOPHEN 325MG /
OXYCODONE 5

Prophylaxis Yes ☐
No ☒

Indication ACUTE KIDNEY INJURY

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:17:05

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		22 OCT 2020
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:17:05

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	20 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy) 22 OCT 2020		
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	803 ☐
	804 ☒	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:17:05

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	20 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	22 OCT 2020	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:17:05

Name of Medication	TRAZODONE
Prophylaxis	Yes ☐ No ☒
Indication	INSOMNIA
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 ☐ Intramuscular ☐

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:17:05

Name of Medication	NITROGLYCERIN
Prophylaxis	Yes ☐ No ☒
Indication	ACUTE KIDNEY INJURY
Dose per administration	04
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:17:05

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☒
If route of administration is Other, specify	SUBLINGUEL	
Start date (dd MMM yyyy)	20 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	20 OCT 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:17:05

Name of Medication	INSULIN GLARGINE
Prophylaxis	Yes ☐ No ☒
Indication	DIABETES MELLITUS TYPE 2
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 ☐ Intramuscular ☐

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:17:05

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		29 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:17:05

Name of Medication	NOVALOG
Prophylaxis	Yes ☐ No ☒
Indication	DIABETES MELLITUS TYPE 2
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	6 TIMES PER DAY Oral ☐ Topical ☐ Subcutaneous ☒ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:17:05

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2008
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3792094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:17:05

[Were any concomitant procedures performed?](#)

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3792094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 11:17:05

Procedure/Surgery date (<i>dd MMM yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
22 OCT 2020	RENAL ULTRASOUND	Adverse Event	
22 OCT 2020	ECHOCARDIOGRAM	Adverse Event	
22 OCT 2020	CHEST X-RAY	Adverse Event	

US3792094

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:17:05

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

US3792094

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:17:05

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 ☐

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

SAEID	USA-US057-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	ABRAM
Investigator's Last Name	BURGHER
Site Address: Street	3900 EAST CAMELBACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:17:05

SAEID	USA-US057-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	ABRAM
Investigator's Last Name	BURGER
Site Address: Street	3900 EAST CAMELBACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	26/OCT/2020 22:02
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

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:17:05

SAEID	USA-US057-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	ABRAM
Investigator's Last Name	BURGER
Site Address: Street	3900 EAST CAMELBACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	05/NOV/2020 19:33
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

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:17:05

SAEID	USA-US057-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	ABRAM
Investigator's Last Name	BURGHEN
Site Address: Street	3900 EAST CAMELBACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	09/NOV/2020 06:50
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3792094 (Prod: Hope Research Institute LLC - Hunt - PPDS)

US3792094

Form: Participant Creation

Generated On: 26 Nov 2020 11:17:05

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3792094'	RWS_ENDPOINT ENDPOINT (b) (4) 	09 Oct 2020 18:52:47

US3792094

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:17:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:43:03

US3792094

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '09 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	09 Oct 2020 18:52:48

US3792094

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:43:03

US3792094

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:17:05

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	09 Oct 2020 19:43:03

US3792094

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:17:05

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1954'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	09 Oct 2020 18:52:49

US3792094

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:17:05

[Age](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 19:50:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 19:50:20
User entered '66' reason for change: Data Entry Error	Norma Frederick (b) (4)	09 Oct 2020 19:50:20
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 19:49:51
User entered empty.	Norma Frederick (b) (4)	09 Oct 2020 19:49:51

US3792094

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:17:05

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	09 Oct 2020 19:50:20
User entered empty.	System	09 Oct 2020 19:49:51

US3792094

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:17:05

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '66'	System	09 Oct 2020 19:43:55

US3792094

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:17:05

Sex

Audit	User	Time (GMT)
User entered 'Male (M)'	Norma Frederick (b) (4)	09 Oct 2020 19:49:51
	(b) (4)	

US3792094

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:17:05

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Norma Frederick (b) (4)	09 Oct 2020 19:49:51

US3792094

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:17:05

White

Audit	User	Time (GMT)
User entered '1'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:49:51

US3792094

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:17:05

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:49:51

US3792094

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:17:05

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4)	09 Oct 2020 19:49:51
	(b) (4)	

US3792094

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:17:05

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:49:51

US3792094

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:17:05

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:49:51

US3792094

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:17:05

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4)	09 Oct 2020 19:49:51
	(b) (4)	

US3792094

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:17:05

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:49:51

US3792094

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:17:05

Unknown

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:49:51

US3792094

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:17:05

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:49:51

US3792094

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:01:46
User entered '9 Oct 2020'	Norma Frederick (b) (4)	09 Oct 2020 19:43:55

US3792094

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'Oct 2020'	System	09 Oct 2020 19:43:55

US3792094

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '2020'	System	09 Oct 2020 19:43:55

US3792094

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:17:05

[Protocol Version](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:01:46
User entered 'Amendment 4 (4)'	Norma Frederick (b) (4)	09 Oct 2020 19:43:55

US3792094

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:01:46
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Oct 2020 19:43:55

US3792094

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:17:05

If No, indicate reason for screen fail

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:01:46
User entered empty.	Norma Frederick (b) (4)	09 Oct 2020 19:43:55

US3792094

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:17:05

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:01:46
User entered empty.	Norma Frederick (b) (4)	09 Oct 2020 19:43:55

US3792094

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:17:05

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:01:46
User entered 'No (N)'	Norma Frederick (b) (4)	09 Oct 2020 19:43:55

US3792094

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:17:05

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:01:46
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	09 Oct 2020 18:52:48

US3792094

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:17:05

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 19:44:03

US3792094

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 20:58:29
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Oct 2020 19:44:03

US3792094

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:17:05

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Oct 2020 19:44:10

US3792094

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:17:05

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Chronic polyneuropathies, PT: Diabetic neuropathy, LLT: Diabetic neuropathy - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 19:23:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 19:23:26
Data point term sent to Coder	System	06 Nov 2020 19:22:16
User entered 'DIABETIC NEUROPATHY'	Norma Frederick (b) (4)	06 Nov 2020 19:21:16

US3792094

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'UN UNK 2011'	Norma Frederick (b) (4)	06 Nov 2020 19:21:16
	(b) (4)	

US3792094

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 19:21:16

US3792094

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:17:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 19:21:16
	(b) (4)	

US3792094

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 19:21:16
	(b) (4)	

US3792094

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:17:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 19:21:16

US3792094

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'Jan 2011'	System	06 Nov 2020 19:21:16

US3792094

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '2011'	System	06 Nov 2020 19:21:16

US3792094

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 19:21:16

US3792094

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 19:21:16

US3792094

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:17:05

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:36:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:36:25
Data point term sent to Coder	System	06 Nov 2020 20:35:10
User entered 'diabetes mellitus, type 2'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:34:42

US3792094

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'un UNK 2001'	Norma Frederick (b) (4)	06 Nov 2020 20:34:42
	(b) (4)	

US3792094

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:34:42

US3792094

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:17:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:34:42
	(b) (4)	

US3792094

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 20:34:42
	(b) (4)	

US3792094

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:17:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:34:42

US3792094

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'Jan 2001'	System	06 Nov 2020 20:34:42

US3792094

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '2001'	System	06 Nov 2020 20:34:42

US3792094

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:34:42

US3792094

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:34:42

US3792094

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:17:05

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 20:36:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 20:36:26
Data point term sent to Coder	System	06 Nov 2020 20:35:09
User entered 'hypertension'	Norma Frederick (b) (4)	06 Nov 2020 20:35:06

US3792094

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:35:06

US3792094

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:35:06

US3792094

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:17:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:35:06
	(b) (4)	

US3792094

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 20:35:06
	(b) (4)	

US3792094

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:17:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:35:06

US3792094

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	06 Nov 2020 20:35:06

US3792094

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '2015'	System	06 Nov 2020 20:35:06

US3792094

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:35:06

US3792094

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:35:06

US3792094

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:17:05

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:37:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:37:21
Data point term sent to Coder	System	06 Nov 2020 20:36:10
User entered 'benign prostatic hyperplasia'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:36:08

US3792094

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Norma Frederick (b) (4)	06 Nov 2020 20:36:08
	(b) (4)	

US3792094

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:36:08

US3792094

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:17:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:36:08
	(b) (4)	

US3792094

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:36:08

US3792094

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:17:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:36:08

US3792094

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	06 Nov 2020 20:36:08

US3792094

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '2015'	System	06 Nov 2020 20:36:08

US3792094

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:36:08

US3792094

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:36:08

US3792094

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:17:05

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 20:38:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 20:38:27
Data point term sent to Coder	System	06 Nov 2020 20:37:12
User entered 'acid reflux'	Norma Frederick (b) (4)	06 Nov 2020 20:36:46

US3792094

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'un UNK 2008'	Norma Frederick (b) (4)	06 Nov 2020 20:36:46
	(b) (4)	

US3792094

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:36:46

US3792094

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:17:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:36:46

US3792094

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 20:36:46
	(b) (4)	

US3792094

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:17:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:36:46

US3792094

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	06 Nov 2020 20:36:46

US3792094

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '2008'	System	06 Nov 2020 20:36:46

US3792094

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:36:46

US3792094

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:36:46

US3792094

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:17:05

[Condition](#)

Audit	User	Time (GMT)
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.	Coder Import (b) (4)	06 Nov 2020 20:38:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 20:38:28
Data point term sent to Coder	System	06 Nov 2020 20:38:13
User entered 'hypercholesterolemia'	Norma Frederick (b) (4)	06 Nov 2020 20:37:34

US3792094

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Norma Frederick (b) (4)	06 Nov 2020 20:37:34
	(b) (4)	

US3792094

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:37:34

US3792094

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:17:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:37:34
	(b) (4)	

US3792094

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:37:34

US3792094

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:17:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:37:34

US3792094

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	06 Nov 2020 20:37:34

US3792094

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '2015'	System	06 Nov 2020 20:37:34

US3792094

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:37:34

US3792094

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:37:34

US3792094

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:17:05

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 20:38:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 20:38:29
Data point term sent to Coder	System	06 Nov 2020 20:38:13
User entered 'insomnia'	Norma Frederick (b) (4)	06 Nov 2020 20:37:54

US3792094

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Norma Frederick (b) (4)	06 Nov 2020 20:37:54
	(b) (4)	

US3792094

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:37:54

US3792094

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:17:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:37:54

US3792094

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 20:37:54
	(b) (4)	

US3792094

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:17:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:37:54

US3792094

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	06 Nov 2020 20:37:54

US3792094

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '2010'	System	06 Nov 2020 20:37:54

US3792094

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:37:54

US3792094

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:37:54

US3792094

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:17:05

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Carpal tunnel syndrome, LLT: Carpal tunnel syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:24:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:24:32
Data point term sent to Coder	System	06 Nov 2020 20:40:15
User entered 'carpal tunnel syndrome, bilateral'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:40:03

US3792094

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'un UNK 2014'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:40:03

US3792094

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:40:03

US3792094

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:17:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:40:03

US3792094

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 20:40:03
	(b) (4)	

US3792094

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:17:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:40:03

US3792094

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	06 Nov 2020 20:40:03

US3792094

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '2014'	System	06 Nov 2020 20:40:03

US3792094

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:40:03

US3792094

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:40:03

US3792094

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:17:05

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 18:59:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 18:59:47
Data point term sent to Coder	System	13 Nov 2020 18:59:09
Coding entries removed.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:59:08
User entered 'CHRONIC OBSTRUCTIVE PULMONARY DISEASE' reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:59:08
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:42:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:42:24
Data point term sent to Coder	System	06 Nov 2020 20:41:18
User entered 'COPD'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:40:25

US3792094

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'un UNK 1975'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:40:25

US3792094

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:40:25

US3792094

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:17:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:40:25
	(b) (4)	

US3792094

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 20:40:25
	(b) (4)	

US3792094

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:17:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:40:25

US3792094

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'Jan 1975'	System	06 Nov 2020 20:40:25

US3792094

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '1975'	System	06 Nov 2020 20:40:25

US3792094

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:40:25

US3792094

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:40:25

US3792094

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:17:05

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Shoulder osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 19:02:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 19:02:48
Data point term sent to Coder	System	13 Nov 2020 19:02:13
User entered 'LEFT SHOULDER OSTEOARTHRITIS'	Scarlett Hammett (b) (4)	13 Nov 2020 19:01:45

US3792094

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'UN UNK 2005'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:01:45

US3792094

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:01:45

US3792094

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:17:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:01:45

US3792094

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:01:45

US3792094

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:17:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:01:45

US3792094

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	13 Nov 2020 19:01:45

US3792094

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '2005'	System	13 Nov 2020 19:01:45

US3792094

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 19:01:45

US3792094

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 19:01:45

US3792094

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:17:05

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal neoplasms, PT: Renal cyst, LLT: Cyst of kidney - version MedDRA\\23.0.	Coder Import (b) (4)	07 Nov 2020 07:07:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	07 Nov 2020 07:07:27
Data point term sent to Coder	System	06 Nov 2020 20:43:20
User entered 'right kidney cyst'	Norma Frederick (b) (4)	06 Nov 2020 20:42:36

US3792094

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:42:36

US3792094

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:42:36

US3792094

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:17:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:42:36

US3792094

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 20:42:36
	(b) (4)	

US3792094

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:17:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:42:36

US3792094

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:42:36

US3792094

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:42:36

US3792094

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:42:36

US3792094

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:42:36

US3792094

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:17:05

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:45:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:45:22
Data point term sent to Coder	System	06 Nov 2020 20:44:23
User entered 'gout'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:43:27

US3792094

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Norma Frederick (b) (4)	06 Nov 2020 20:43:27
	(b) (4)	

US3792094

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:43:27

US3792094

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:17:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:43:27
	(b) (4)	

US3792094

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:43:27

US3792094

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:17:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:43:27

US3792094

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	06 Nov 2020 20:43:27

US3792094

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '2010'	System	06 Nov 2020 20:43:27

US3792094

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:43:27

US3792094

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:43:27

US3792094

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:17:05

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:45:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:45:23
Data point term sent to Coder	System	06 Nov 2020 20:44:23
User entered 'obesity'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:43:44

US3792094

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'un UNK 1972'	Norma Frederick (b) (4)	06 Nov 2020 20:43:44
	(b) (4)	

US3792094

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:43:44

US3792094

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:17:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:43:44
	(b) (4)	

US3792094

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:43:44

US3792094

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:17:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:43:44

US3792094

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'Jan 1972'	System	06 Nov 2020 20:43:44

US3792094

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '1972'	System	06 Nov 2020 20:43:44

US3792094

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:43:44

US3792094

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:43:44

US3792094

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:17:05

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Tinnitus, LLT: Tinnitus - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 20:45:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 20:45:22
Data point term sent to Coder	System	06 Nov 2020 20:44:23
User entered 'tinnitus'	Norma Frederick (b) (4)	06 Nov 2020 20:44:23

US3792094

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'un UNK 2009'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:44:23

US3792094

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:44:23

US3792094

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:17:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:44:23
	(b) (4)	

US3792094

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:44:23

US3792094

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:17:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:44:23

US3792094

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'Jan 2009'	System	06 Nov 2020 20:44:23

US3792094

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '2009'	System	06 Nov 2020 20:44:23

US3792094

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:44:23

US3792094

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:44:23

US3792094

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:17:05

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Foot fracture, LLT: Foot fracture - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 08:58:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 08:58:33
Data point term sent to Coder	System	06 Nov 2020 20:45:27
User entered 'closed fracture of phalanx of left 3rd toe'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:45:06

US3792094

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '01 Sep 2020'	Norma Frederick (b) (4)	06 Nov 2020 20:45:06
	(b) (4)	

US3792094

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:45:06

US3792094

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:17:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:45:06
	(b) (4)	

US3792094

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:45:06

US3792094

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:17:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:45:06

US3792094

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	06 Nov 2020 20:45:06

US3792094

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '2020'	System	06 Nov 2020 20:45:06

US3792094

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:45:06

US3792094

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:45:06

US3792094

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:17:05

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Eye disorders, HLGT: Retina, choroid and vitreous haemorrhages and vascular disorders, HLT: Retinopathies NEC, PT: Diabetic retinopathy, LLT: Diabetic retinopathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 23:45:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 23:45:26
Data point term sent to Coder	System	06 Nov 2020 20:46:28
User entered 'diabetic retinopathy of both eyes'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:45:40

US3792094

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '18 Jun 2020'	Norma Frederick (b) (4)	06 Nov 2020 20:45:40
	(b) (4)	

US3792094

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:45:40

US3792094

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:17:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:45:40
	(b) (4)	

US3792094

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 20:45:40
	(b) (4)	

US3792094

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:17:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:45:40

US3792094

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'Jun 2020'	System	06 Nov 2020 20:45:40

US3792094

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '2020'	System	06 Nov 2020 20:45:40

US3792094

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:45:40

US3792094

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:45:40

US3792094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:17:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Oct 2020 19:46:08
	(b) (4)	

US3792094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '9 Oct 2020'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:46:08

US3792094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '12:29'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:46:08

US3792094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '9 Oct 2020 12:29'	System	09 Oct 2020 19:46:08

US3792094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '68.5' in	Norma Frederick (b) (4)	09 Oct 2020 19:46:08
DataPoint set to visible.	(b) (4) System	09 Oct 2020 19:44:03

US3792094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '330.0' lb	Norma Frederick (b) (4)	09 Oct 2020 19:46:08
DataPoint set to visible.	(b) (4) System	09 Oct 2020 19:44:03

US3792094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:17:05

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '49.54989'	System	09 Oct 2020 19:46:08
DataPoint set to visible.	System	09 Oct 2020 19:44:03

US3792094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:17:05

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	09 Oct 2020 19:46:08
DataPoint set to visible.	System	09 Oct 2020 19:44:03

US3792094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:17:05

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Norma Frederick (b) (4)	09 Oct 2020 19:46:08
	(b) (4)	

US3792094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:17:05

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:46:08

US3792094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:17:05

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:46:08

US3792094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:17:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:46:08

US3792094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:17:05

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Oct 2020 19:46:08

US3792094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:46:08

US3792094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:17:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Oct 2020 19:46:08

US3792094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:17:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:46:08

US3792094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:17:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Oct 2020 19:46:08

US3792094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:17:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:46:08

US3792094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:17:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Oct 2020 19:46:08

US3792094

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:17:05

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Oct 2020 19:46:16
	(b) (4)	

US3792094

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:17:05

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '9 Oct 2020'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:46:16

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4)	09 Oct 2020 19:47:05

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:47:05

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4)	09 Oct 2020 19:47:05
	(b) (4)	

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4)	09 Oct 2020 19:47:05
	(b) (4)	

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4)	09 Oct 2020 19:47:05
	(b) (4)	

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4)	09 Oct 2020 19:47:05
	(b) (4)	

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4)	09 Oct 2020 19:47:05
	(b) (4)	

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4)	09 Oct 2020 19:47:05

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:47:05

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4)	09 Oct 2020 19:47:05

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4)	09 Oct 2020 19:47:05

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:17:05

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Oct 2020 19:47:05
	(b) (4)	

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:17:05

[Specify](#)

Audit	User	Time (GMT)
User entered 'wares vendor at (b) (6)	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:47:05

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:17:05

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:47:05

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:47:05

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4)	09 Oct 2020 19:47:05
	(b) (4)	

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:47:05

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4)	09 Oct 2020 19:47:05
	(b) (4)	

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:47:05

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:17:05

[Other](#)

Audit	User	Time (GMT)
User entered '1'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:47:05

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:17:05

[Specify](#)

Audit	User	Time (GMT)
User entered 'mobile home'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:47:05

US3792094

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:17:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Oct 2020 19:47:23
	(b) (4)	

US3792094

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '9 Oct 2020'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:47:23

US3792094

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:47:23

US3792094

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:17:05

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	09 Oct 2020 19:47:23

US3792094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '09 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	09 Oct 2020 19:47:41

US3792094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '191513'	RWS_ENDPOINT ENDPOINT (b) (4) 	09 Oct 2020 19:47:41

US3792094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) 	09 Oct 2020 19:47:41

US3792094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Oct 2020 19:47:48

US3792094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4)	09 Oct 2020 19:47:48

US3792094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:47:48

US3792094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:17:05

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Oct 2020 19:47:48
	(b) (4)	

US3792094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:17:05

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:47:48

US3792094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4)	09 Oct 2020 19:47:48
DataPoint set to visible.	(b) (4) System	09 Oct 2020 19:43:55

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:17:05

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Norma Frederick (b) (4)	09 Oct 2020 19:51:52
	(b) (4)	

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:17:05

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:17:05

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:17:05

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:17:05

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Norma Frederick (b) (4)	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:17:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Oct 2020 19:51:52
	(b) (4)	

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:17:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '9 Oct 2020'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '12:29'	Norma Frederick (b) (4)	09 Oct 2020 19:51:52
	(b) (4)	

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '9 Oct 2020 12:29'	System	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:17:05

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.6' F	Norma Frederick (b) (4)	09 Oct 2020 19:51:52
	(b) (4)	

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:17:05

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:17:05

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:17:05

Pulse (xxx)

Audit	User	Time (GMT)
User entered '57'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:17:05

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '15'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:17:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:17:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '154'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:17:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:17:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '85'	Norma Frederick (b) (4)	09 Oct 2020 19:51:52
	(b) (4)	

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:17:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:17:05

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:17:05

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:17:05

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Norma Frederick (b) (4)	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:17:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 23:52:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Nov 2020 23:52:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Norma Frederick (b) (4)	04 Nov 2020 23:52:59
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 19:51:52
User entered empty.	Norma Frederick (b) (4)	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:17:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '9 Oct 2020' reason for change: Data Entry Error	Norma Frederick (b) (4)	04 Nov 2020 23:52:59
User entered empty.	Norma Frederick (b) (4)	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '13:37' reason for change: Data Entry Error	Norma Frederick (b) (4)	04 Nov 2020 23:52:59
User entered empty.	Norma Frederick (b) (4)	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '9 Oct 2020 13:37'	System	04 Nov 2020 23:52:59
User entered empty.	System	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:17:05

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.1' F reason for change: Data Entry Error	Norma Frederick (b) (4)	04 Nov 2020 23:52:59
User entered empty.	Norma Frederick (b) (4)	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:17:05

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	Norma Frederick (b) (4)	04 Nov 2020 23:52:59
User entered empty.	Norma Frederick (b) (4)	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:17:05

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:17:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '64' reason for change: Data Entry Error	Norma Frederick (b) (4)	04 Nov 2020 23:52:59
User entered empty.	Norma Frederick (b) (4)	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:17:05

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	04 Nov 2020 23:52:59
User entered empty.	System	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '16' reason for change: Data Entry Error	Norma Frederick (b) (4)	04 Nov 2020 23:52:59
User entered empty.	Norma Frederick (b) (4)	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:17:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	04 Nov 2020 23:52:59
User entered empty.	System	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:17:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Per CDM: Systolic BP is out of range <80 or >155 is considered as grade 3 per protocol. Please indicate if CS or NCS and report as AE, if appropriate or else clarif' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 20:39:29
Query 'Per CDM: Systolic BP is out of range <80 or >155 is considered as grade 3 per protocol. Please indicate if CS or NCS and report as AE, if appropriate or else clarif' answered with 'Per Sub-I bp is NCS' (Site from DM).	Ann Marie Milliken (b) (4)	18 Nov 2020 19:07:39
User opened query 'Per CDM: Systolic BP is out of range <80 or >155 is considered as grade 3 per protocol. Please indicate if CS or NCS and report as AE, if appropriate or else clarif' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 20:47:55
User entered '167' reason for change: Data Entry Error	Norma Frederick (b) (4)	04 Nov 2020 23:52:59
User entered empty.	Norma Frederick (b) (4)	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:17:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Nov 2020 23:52:59
User entered empty.	System	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '92' reason for change: Data Entry Error	Norma Frederick (b) (4)	04 Nov 2020 23:52:59
User entered empty.	Norma Frederick (b) (4)	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:17:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Nov 2020 23:52:59
User entered empty.	System	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:17:05

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:48:34

US3792094

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:17:05

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:48:34

US3792094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:17:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Oct 2020 20:16:54
	(b) (4)	

US3792094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:17:05

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 20:16:54

US3792094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4)	09 Oct 2020 20:16:54

US3792094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:17:05

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	09 Oct 2020 20:16:54

US3792094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:17:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '9 Oct 2020'	Norma Frederick (b) (4)	09 Oct 2020 20:16:54
	(b) (4)	

US3792094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '13:08'	Norma Frederick (b) (4)	09 Oct 2020 20:16:54
	(b) (4)	

US3792094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '9 Oct 2020 13:08'	System	09 Oct 2020 20:16:54

US3792094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Norma Frederick (b) (4)	09 Oct 2020 20:16:54

US3792094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	09 Oct 2020 20:16:54

US3792094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:17:05

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	09 Oct 2020 20:16:54

US3792094

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:17:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Oct 2020 19:49:25

US3792094

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:17:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit1 Day 1 is recorded as 09-OCT-2020. However, collection date is missing in GCL. Please confirm if 09-OCT-2020 is correct date to update in GCL records.' answered with 'confirmed visit date is 10/9/2020' (Site from DM).	Norma Frederick (b) (4)	05 Nov 2020 01:35:33
User opened query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit1 Day 1 is recorded as 09-OCT-2020. However, collection date is missing in GCL. Please confirm if 09-OCT-2020 is correct date to update in GCL records.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 07:52:47
User entered '9 Oct 2020'	Norma Frederick (b) (4)	09 Oct 2020 19:49:25

US3792094

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:17:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '12:33'	Norma Frederick (b) (4)	09 Oct 2020 19:49:25
	(b) (4)	

US3792094

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '9 Oct 2020 12:33'	System	09 Oct 2020 19:49:25

US3792094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:17:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '9 Oct 2020'	Norma Frederick (b) (4)	09 Oct 2020 19:49:00
	(b) (4)	

US3792094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:17:05

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Norma Frederick (b) (4)	09 Oct 2020 19:49:00

US3792094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:17:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Oct 2020 19:49:00
	(b) (4)	

US3792094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:17:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '12:38'	Norma Frederick (b) (4)	09 Oct 2020 19:49:00
	(b) (4)	

US3792094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '9 Oct 2020 12:38'	System	09 Oct 2020 19:49:00

US3792094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:17:05

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Norma Frederick (b) (4)	09 Oct 2020 19:49:00

US3792094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:17:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4)	09 Oct 2020 19:49:00
	(b) (4)	

US3792094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:17:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4)	09 Oct 2020 19:49:00
	(b) (4)	

US3792094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 19:49:00

US3792094

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Oct 2020 19:48:41
	(b) (4)	

US3792094

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:17:05

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 19:48:41

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:45:38', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5ca55cf6-5cef-4004-bb73-83a3340116a8'	System	09 Oct 2020 20:48:56
User entered 'Yes (Y)'	System	09 Oct 2020 20:48:56

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:47:44', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5ca55cf6-5cef-4004-bb73-83a3340116a8'	System	09 Oct 2020 20:48:56
User entered '98.1'	System	09 Oct 2020 20:48:56

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:47:51', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5ca55cf6-5cef-4004-bb73-83a3340116a8'	System	09 Oct 2020 20:48:56
User entered 'Yes (Y)'	System	09 Oct 2020 20:48:56

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
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 'This was recorded in error' (Site from System).	(b) (4), (b) (6)	22 Nov 2020 10:07:49
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).	Ann Marie Milliken	18 Nov 2020 19:09:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:48:01', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5ca55cf6-5cef-4004-bb73-83a3340116a8'	(b) (4)	
User entered '1'	System	09 Oct 2020 20:48:56
	System	09 Oct 2020 20:48:56
	System	09 Oct 2020 20:48:56

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'This was recorded in error.' (Site from System).	(b) (4), (b) (6)	22 Nov 2020 10:07:53
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:48:01', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5ca55cf6-5cef-4004-bb73-83a3340116a8'	Ann Marie Milliken (b) (4)	18 Nov 2020 19:09:59
User entered '1'	System	09 Oct 2020 20:48:56

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:48:50', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5ca55cf6-5cef-4004-bb73-83a3340116a8'	System	09 Oct 2020 20:48:56
User entered '09 Oct 2020 13:48'	System	09 Oct 2020 20:48:56

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 13:28'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 15:58'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T16:55:53', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'a50280d7-e648-406f-9e43-1e734d188fc0'	System	09 Oct 2020 23:56:23
User entered 'Yes (Y)'	System	09 Oct 2020 23:56:23

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T16:56:03', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'a50280d7-e648-406f-9e43-1e734d188fc0'	System	09 Oct 2020 23:56:23
User entered '96.8'	System	09 Oct 2020 23:56:23

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T16:56:11', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'a50280d7-e648-406f-9e43-1e734d188fc0'	System	09 Oct 2020 23:56:23
User entered 'No (N)'	System	09 Oct 2020 23:56:23

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T16:56:18', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'a50280d7-e648-406f-9e43-1e734d188fc0'	System	09 Oct 2020 23:56:23
User entered '09 Oct 2020 16:56'	System	09 Oct 2020 23:56:23

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 16:53'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 2'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:17:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:01:56', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '719d3b92-bcd9-4f03-9cf7-64e47e871717'	System	10 Oct 2020 19:02:54
User entered 'Yes (Y)'	System	10 Oct 2020 19:02:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:17:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:02:08', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '719d3b92-bcd9-4f03-9cf7-64e47e871717'	System	10 Oct 2020 19:02:54
User entered '97.5'	System	10 Oct 2020 19:02:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:02:23', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '719d3b92-bcd9-4f03-9cf7-64e47e871717'	System	10 Oct 2020 19:02:54
User entered 'Yes (Y)'	System	10 Oct 2020 19:02:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
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 'This was recorded in error' (Site from System).	(b) (4), (b) (6)	22 Nov 2020 10:08:05
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 (88c81b8af040f89c)', Time: '2020-10-10T12:02:35', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '719d3b92-bcd9-4f03-9cf7-64e47e871717'	Ann Marie Milliken (b) (4)	18 Nov 2020 19:10:38
User entered '1'	System	10 Oct 2020 19:02:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:17:05

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:02:35', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '719d3b92-bcd9-4f03-9cf7-64e47e871717'	System	10 Oct 2020 19:02:54
User entered '0'	System	10 Oct 2020 19:02:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:17:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:02:49', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '719d3b92-bcd9-4f03-9cf7-64e47e871717'	System	10 Oct 2020 19:02:54
User entered '10 Oct 2020 12:02'	System	10 Oct 2020 19:02:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 3'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:17:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-11T16:02:28', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'ad5df36b-b03c-456f-8b2d-ee839fdf64b8'	System	11 Oct 2020 23:02:51
User entered 'Yes (Y)'	System	11 Oct 2020 23:02:51

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:17:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-11T16:02:35', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'ad5df36b-b03c-456f-8b2d-ee839fdf64b8'	System	11 Oct 2020 23:02:51
User entered '97.5'	System	11 Oct 2020 23:02:51

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-11T16:02:42', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'ad5df36b-b03c-456f-8b2d-ee839fdf64b8'	System	11 Oct 2020 23:02:51
User entered 'No (N)'	System	11 Oct 2020 23:02:51

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:17:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-11T16:02:48', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'ad5df36b-b03c-456f-8b2d-ee839fdf64b8'	System	11 Oct 2020 23:02:51
User entered '11 Oct 2020 16:02'	System	11 Oct 2020 23:02:51

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 4'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:17:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-12T12:28:45', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'c959652c-066f-482d-be87-1440626840d1'	System	12 Oct 2020 19:29:25
User entered 'Yes (Y)'	System	12 Oct 2020 19:29:25

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:17:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-12T12:28:52', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'c959652c-066f-482d-be87-1440626840d1'	System	12 Oct 2020 19:29:25
User entered '97.5'	System	12 Oct 2020 19:29:25

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-12T12:29:12', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'c959652c-066f-482d-be87-1440626840d1'	System	12 Oct 2020 19:29:25
User entered 'No (N)'	System	12 Oct 2020 19:29:25

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:17:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-12T12:29:22', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'c959652c-066f-482d-be87-1440626840d1'	System	12 Oct 2020 19:29:25
User entered '12 Oct 2020 12:29'	System	12 Oct 2020 19:29:25

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 5'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:17:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-13T13:05:12', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '789e37eb-5c78-4b27-ac20-ae17b0a12f31'	System	13 Oct 2020 20:05:31
User entered 'Yes (Y)'	System	13 Oct 2020 20:05:31

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:17:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-13T13:05:19', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '789e37eb-5c78-4b27-ac20-ae17b0a12f31'	System	13 Oct 2020 20:05:31
User entered '95.5'	System	13 Oct 2020 20:05:31

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-13T13:05:23', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '789e37eb-5c78-4b27-ac20-ae17b0a12f31'	System	13 Oct 2020 20:05:31
User entered 'No (N)'	System	13 Oct 2020 20:05:31

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:17:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-13T13:05:28', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '789e37eb-5c78-4b27-ac20-ae17b0a12f31'	System	13 Oct 2020 20:05:31
User entered '13 Oct 2020 13:05'	System	13 Oct 2020 20:05:31

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 6'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:17:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-14T12:35:25', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8726df91-77da-4d32-9f77-f714c20869d2'	System	14 Oct 2020 19:35:52
User entered 'Yes (Y)'	System	14 Oct 2020 19:35:52

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:17:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-14T12:35:36', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8726df91-77da-4d32-9f77-f714c20869d2'	System	14 Oct 2020 19:35:52
User entered '97.0'	System	14 Oct 2020 19:35:52

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-14T12:35:42', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8726df91-77da-4d32-9f77-f714c20869d2'	System	14 Oct 2020 19:35:52
User entered 'No (N)'	System	14 Oct 2020 19:35:52

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:17:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-14T12:35:48', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8726df91-77da-4d32-9f77-f714c20869d2'	System	14 Oct 2020 19:35:52
User entered '14 Oct 2020 12:35'	System	14 Oct 2020 19:35:52

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 7'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:17:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-15T17:01:08', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '44cb4832-a902-475c-b80d-8065264a127f'	System	16 Oct 2020 00:01:32
User entered 'Yes (Y)'	System	16 Oct 2020 00:01:32

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:17:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-15T17:01:17', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '44cb4832-a902-475c-b80d-8065264a127f' User entered '97.8'	System	16 Oct 2020 00:01:32

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-15T17:01:23', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '44cb4832-a902-475c-b80d-8065264a127f'	System	16 Oct 2020 00:01:32
User entered 'No (N)'	System	16 Oct 2020 00:01:32

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:17:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-15T17:01:27', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '44cb4832-a902-475c-b80d-8065264a127f' User entered '15 Oct 2020 17:01'	System	16 Oct 2020 00:01:32

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:49:17', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5d9eefe4-6e94-454c-9edd-1d16754f593d'	System	09 Oct 2020 20:51:07
User entered 'None (1)'	System	09 Oct 2020 20:51:07

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:50:33', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5d9eefe4-6e94-454c-9edd-1d16754f593d'	System	09 Oct 2020 20:51:07
User entered 'No (N)'	System	09 Oct 2020 20:51:07

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:50:38', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5d9eefe4-6e94-454c-9edd-1d16754f593d'	System	09 Oct 2020 20:51:07
User entered 'No (N)'	System	09 Oct 2020 20:51:07

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:50:49', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5d9eefe4-6e94-454c-9edd-1d16754f593d'	System	09 Oct 2020 20:51:07
User entered 'None (1)'	System	09 Oct 2020 20:51:07

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:50:58', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5d9eefe4-6e94-454c-9edd-1d16754f593d'	System	09 Oct 2020 20:51:07
User entered '09 Oct 2020 13:50'	System	09 Oct 2020 20:51:07

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 13:28'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 15:58'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T16:56:25', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8b44256d-50e9-4c4e-a1d2-eeeeee06c458b'	System	09 Oct 2020 23:56:56
User entered 'None (1)'	System	09 Oct 2020 23:56:56

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T16:56:29', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8b44256d-50e9-4c4e-a1d2-eeeeee06c458b'	System	09 Oct 2020 23:56:56
User entered 'No (N)'	System	09 Oct 2020 23:56:56

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T16:56:36', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8b44256d-50e9-4c4e-a1d2-eeeeee06c458b'	System	09 Oct 2020 23:56:56
User entered 'No (N)'	System	09 Oct 2020 23:56:56

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T16:56:47', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8b44256d-50e9-4c4e-a1d2-eeeeee06c458b'	System	09 Oct 2020 23:56:56
User entered 'None (1)'	System	09 Oct 2020 23:56:56

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T16:56:51', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8b44256d-50e9-4c4e-a1d2-eeeeee06c458b'	System	09 Oct 2020 23:56:56
User entered '09 Oct 2020 16:56'	System	09 Oct 2020 23:56:56

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 16:53'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 2'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:17:05

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:03:33', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'c0dd7105-89fb-4e82-8675-837009ad6814'	System	10 Oct 2020 19:04:01
User entered 'None (1)'	System	10 Oct 2020 19:04:01

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:17:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:03:37', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'c0dd7105-89fb-4e82-8675-837009ad6814'	System	10 Oct 2020 19:04:01
User entered 'No (N)'	System	10 Oct 2020 19:04:01

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:03:41', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'c0dd7105-89fb-4e82-8675-837009ad6814'	System	10 Oct 2020 19:04:01
User entered 'No (N)'	System	10 Oct 2020 19:04:01

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:17:05

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:03:50', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'c0dd7105-89fb-4e82-8675-837009ad6814'	System	10 Oct 2020 19:04:01
User entered 'None (1)'	System	10 Oct 2020 19:04:01

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:17:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:03:55', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'c0dd7105-89fb-4e82-8675-837009ad6814'	System	10 Oct 2020 19:04:01
User entered '10 Oct 2020 12:03'	System	10 Oct 2020 19:04:01

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 3'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:17:05

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-11T16:02:55', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f6df2fdd-04b8-4741-8ed3-4d5ee8f0e26b'	System	11 Oct 2020 23:03:18
User entered 'None (1)'	System	11 Oct 2020 23:03:18

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:17:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-11T16:02:59', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f6df2fdd-04b8-4741-8ed3-4d5ee8f0e26b'	System	11 Oct 2020 23:03:18
User entered 'No (N)'	System	11 Oct 2020 23:03:18

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-11T16:03:03', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f6df2fdd-04b8-4741-8ed3-4d5ee8f0e26b'	System	11 Oct 2020 23:03:18
User entered 'No (N)'	System	11 Oct 2020 23:03:18

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:17:05

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-11T16:03:10', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f6df2fdd-04b8-4741-8ed3-4d5ee8f0e26b'	System	11 Oct 2020 23:03:18
User entered 'None (1)'	System	11 Oct 2020 23:03:18

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:17:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-11T16:03:15', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f6df2fdd-04b8-4741-8ed3-4d5ee8f0e26b'	System	11 Oct 2020 23:03:18
User entered '11 Oct 2020 16:03'	System	11 Oct 2020 23:03:18

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 4'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:17:05

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-12T12:29:31', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '34848fb7-2e8f-4d70-a950-9ad36d7b617c'	System	12 Oct 2020 19:29:53
User entered 'None (1)'	System	12 Oct 2020 19:29:53

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:17:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-12T12:29:35', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '34848fb7-2e8f-4d70-a950-9ad36d7b617c'	System	12 Oct 2020 19:29:53
User entered 'No (N)'	System	12 Oct 2020 19:29:53

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-12T12:29:41', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '34848fb7-2e8f-4d70-a950-9ad36d7b617c'	System	12 Oct 2020 19:29:53
User entered 'No (N)'	System	12 Oct 2020 19:29:53

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:17:05

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-12T12:29:45', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '34848fb7-2e8f-4d70-a950-9ad36d7b617c'	System	12 Oct 2020 19:29:53
User entered 'None (1)'	System	12 Oct 2020 19:29:53

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:17:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-12T12:29:50', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '34848fb7-2e8f-4d70-a950-9ad36d7b617c'	System	12 Oct 2020 19:29:53
User entered '12 Oct 2020 12:29'	System	12 Oct 2020 19:29:53

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 5'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:17:05

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-13T13:05:34', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '3a4feebc-380c-49d3-91fe-308c1a5fcaaf'	System	13 Oct 2020 20:06:00
User entered 'None (1)'	System	13 Oct 2020 20:06:00

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:17:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-13T13:05:38', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '3a4feebc-380c-49d3-91fe-308c1a5fcaaf'	System	13 Oct 2020 20:06:00
User entered 'No (N)'	System	13 Oct 2020 20:06:00

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-13T13:05:44', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '3a4feebc-380c-49d3-91fe-308c1a5fcaaf'	System	13 Oct 2020 20:06:00
User entered 'No (N)'	System	13 Oct 2020 20:06:00

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:17:05

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-13T13:05:52', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '3a4feebc-380c-49d3-91fe-308c1a5fcaaf'	System	13 Oct 2020 20:06:00
User entered 'None (1)'	System	13 Oct 2020 20:06:00

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:17:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-13T13:05:57', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '3a4feebc-380c-49d3-91fe-308c1a5fcaaf'	System	13 Oct 2020 20:06:00
User entered '13 Oct 2020 13:05'	System	13 Oct 2020 20:06:00

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 6'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:17:05

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-14T12:35:55', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '3d93cdc2-9c0e-4ee8-8e27-ee80129a8151'	System	14 Oct 2020 19:36:31
User entered 'None (1)'	System	14 Oct 2020 19:36:31

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:17:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-14T12:36:01', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '3d93cdc2-9c0e-4ee8-8e27-ee80129a8151'	System	14 Oct 2020 19:36:31
User entered 'No (N)'	System	14 Oct 2020 19:36:31

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-14T12:36:07', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '3d93cdc2-9c0e-4ee8-8e27-ee80129a8151'	System	14 Oct 2020 19:36:31
User entered 'No (N)'	System	14 Oct 2020 19:36:31

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:17:05

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-14T12:36:21', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '3d93cdc2-9c0e-4ee8-8e27-ee80129a8151'	System	14 Oct 2020 19:36:31
User entered 'None (1)'	System	14 Oct 2020 19:36:31

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:17:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-14T12:36:28', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '3d93cdc2-9c0e-4ee8-8e27-ee80129a8151'	System	14 Oct 2020 19:36:31
User entered '14 Oct 2020 12:36'	System	14 Oct 2020 19:36:31

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 7'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:17:05

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-15T17:01:34', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'dba20477-7006-47de-ba17-fafe2f688a93'	System	16 Oct 2020 00:02:03
User entered 'None (1)'	System	16 Oct 2020 00:02:03

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:17:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-15T17:01:39', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'dba20477-7006-47de-ba17-fafe2f688a93'	System	16 Oct 2020 00:02:03
User entered 'No (N)'	System	16 Oct 2020 00:02:03

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-15T17:01:44', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'dba20477-7006-47de-ba17-fafe2f688a93'	System	16 Oct 2020 00:02:03
User entered 'No (N)'	System	16 Oct 2020 00:02:03

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:17:05

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-15T17:01:53', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'dba20477-7006-47de-ba17-fafe2f688a93'	System	16 Oct 2020 00:02:03
User entered 'None (1)'	System	16 Oct 2020 00:02:03

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:17:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-15T17:01:57', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'dba20477-7006-47de-ba17-fafe2f688a93'	System	16 Oct 2020 00:02:03
User entered '15 Oct 2020 17:01'	System	16 Oct 2020 00:02:03

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:51:04', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '78be4bbe-c284-4ae3-b4ac-566a3810ba0a'	System	09 Oct 2020 20:51:43
User entered 'None (0)'	System	09 Oct 2020 20:51:43

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:51:08', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '78be4bbe-c284-4ae3-b4ac-566a3810ba0a'	System	09 Oct 2020 20:51:43
User entered 'None (0)'	System	09 Oct 2020 20:51:43

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:51:12', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '78be4bbe-c284-4ae3-b4ac-566a3810ba0a'	System	09 Oct 2020 20:51:43
User entered 'None (0)'	System	09 Oct 2020 20:51:43

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:51:18', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '78be4bbe-c284-4ae3-b4ac-566a3810ba0a'	System	09 Oct 2020 20:51:43
User entered 'None (0)'	System	09 Oct 2020 20:51:43

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:51:21', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '78be4bbe-c284-4ae3-b4ac-566a3810ba0a'	System	09 Oct 2020 20:51:43
User entered 'None (0)'	System	09 Oct 2020 20:51:43

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:51:23', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '78be4bbe-c284-4ae3-b4ac-566a3810ba0a'	System	09 Oct 2020 20:51:43
User entered 'None (0)'	System	09 Oct 2020 20:51:43

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:51:28', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '78be4bbe-c284-4ae3-b4ac-566a3810ba0a'	System	09 Oct 2020 20:51:43
User entered 'No (N)'	System	09 Oct 2020 20:51:43

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:51:38', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '78be4bbe-c284-4ae3-b4ac-566a3810ba0a'	System	09 Oct 2020 20:51:43
User entered '09 Oct 2020 13:51'	System	09 Oct 2020 20:51:43

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 13:28'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 15:58'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T16:57:22', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'cd63350c-f7d3-4edf-9884-8df93765acc4'	System	09 Oct 2020 23:58:02
User entered 'None (0)'	System	09 Oct 2020 23:58:02

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T16:57:27', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'cd63350c-f7d3-4edf-9884-8df93765acc4'	System	09 Oct 2020 23:58:02
User entered 'None (0)'	System	09 Oct 2020 23:58:02

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T16:57:30', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'cd63350c-f7d3-4edf-9884-8df93765acc4'	System	09 Oct 2020 23:58:02
User entered 'None (0)'	System	09 Oct 2020 23:58:02

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T16:57:35', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'cd63350c-f7d3-4edf-9884-8df93765acc4'	System	09 Oct 2020 23:58:02
User entered 'None (0)'	System	09 Oct 2020 23:58:02

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T16:57:38', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'cd63350c-f7d3-4edf-9884-8df93765acc4'	System	09 Oct 2020 23:58:02
User entered 'None (0)'	System	09 Oct 2020 23:58:02

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T16:57:41', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'cd63350c-f7d3-4edf-9884-8df93765acc4'	System	09 Oct 2020 23:58:02
User entered 'None (0)'	System	09 Oct 2020 23:58:02

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T16:57:48', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'cd63350c-f7d3-4edf-9884-8df93765acc4'	System	09 Oct 2020 23:58:02
User entered 'No (N)'	System	09 Oct 2020 23:58:02

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T16:57:57', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'cd63350c-f7d3-4edf-9884-8df93765acc4'	System	09 Oct 2020 23:58:02
User entered '09 Oct 2020 16:57'	System	09 Oct 2020 23:58:02

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 16:53'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 2'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:17:05

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:04:01', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '24033187-85df-480c-a009-f743aa5a7222'	System	10 Oct 2020 19:04:37
User entered 'None (0)'	System	10 Oct 2020 19:04:37

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:17:05

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:04:05', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '24033187-85df-480c-a009-f743aa5a7222'	System	10 Oct 2020 19:04:37
User entered 'None (0)'	System	10 Oct 2020 19:04:37

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:17:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:04:09', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '24033187-85df-480c-a009-f743aa5a7222'	System	10 Oct 2020 19:04:37
User entered 'None (0)'	System	10 Oct 2020 19:04:37

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:17:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:04:12', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '24033187-85df-480c-a009-f743aa5a7222'	System	10 Oct 2020 19:04:37
User entered 'None (0)'	System	10 Oct 2020 19:04:37

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:17:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:04:16', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '24033187-85df-480c-a009-f743aa5a7222'	System	10 Oct 2020 19:04:37
User entered 'None (0)'	System	10 Oct 2020 19:04:37

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:17:05

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:04:18', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '24033187-85df-480c-a009-f743aa5a7222'	System	10 Oct 2020 19:04:37
User entered 'None (0)'	System	10 Oct 2020 19:04:37

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:04:25', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '24033187-85df-480c-a009-f743aa5a7222'	System	10 Oct 2020 19:04:37
User entered 'No (N)'	System	10 Oct 2020 19:04:37

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:17:05

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:04:32', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '24033187-85df-480c-a009-f743aa5a7222'	System	10 Oct 2020 19:04:37
User entered '10 Oct 2020 12:04'	System	10 Oct 2020 19:04:37

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 3'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:17:05

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-11T16:03:19', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '901bbf07-7dc8-4251-b48b-60e1537bb085'	System	11 Oct 2020 23:03:49
User entered 'None (0)'	System	11 Oct 2020 23:03:49

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:17:05

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-11T16:03:22', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '901bbf07-7dc8-4251-b48b-60e1537bb085'	System	11 Oct 2020 23:03:49
User entered 'None (0)'	System	11 Oct 2020 23:03:49

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:17:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-11T16:03:26', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '901bbf07-7dc8-4251-b48b-60e1537bb085'	System	11 Oct 2020 23:03:49
User entered 'None (0)'	System	11 Oct 2020 23:03:49

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:17:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-11T16:03:30', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '901bbf07-7dc8-4251-b48b-60e1537bb085'	System	11 Oct 2020 23:03:49
User entered 'None (0)'	System	11 Oct 2020 23:03:49

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:17:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-11T16:03:33', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '901bbf07-7dc8-4251-b48b-60e1537bb085'	System	11 Oct 2020 23:03:49
User entered 'None (0)'	System	11 Oct 2020 23:03:49

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:17:05

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-11T16:03:35', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '901bbf07-7dc8-4251-b48b-60e1537bb085'	System	11 Oct 2020 23:03:49
User entered 'None (0)'	System	11 Oct 2020 23:03:49

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-11T16:03:39', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '901bbf07-7dc8-4251-b48b-60e1537bb085'	System	11 Oct 2020 23:03:49
User entered 'No (N)'	System	11 Oct 2020 23:03:49

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:17:05

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-11T16:03:44', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '901bbf07-7dc8-4251-b48b-60e1537bb085'	System	11 Oct 2020 23:03:49
User entered '11 Oct 2020 16:03'	System	11 Oct 2020 23:03:49

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 4'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:17:05

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-12T12:29:56', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '6d45bc4a-85b3-4e0b-9a75-28a3780e5965'	System	12 Oct 2020 19:30:39
User entered 'None (0)'	System	12 Oct 2020 19:30:39

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:17:05

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-12T12:30:04', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '6d45bc4a-85b3-4e0b-9a75-28a3780e5965'	System	12 Oct 2020 19:30:39
User entered 'None (0)'	System	12 Oct 2020 19:30:39

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:17:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-12T12:30:07', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '6d45bc4a-85b3-4e0b-9a75-28a3780e5965'	System	12 Oct 2020 19:30:39
User entered 'None (0)'	System	12 Oct 2020 19:30:39

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:17:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-12T12:30:16', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '6d45bc4a-85b3-4e0b-9a75-28a3780e5965'	System	12 Oct 2020 19:30:39
User entered 'None (0)'	System	12 Oct 2020 19:30:39

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:17:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-12T12:30:20', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '6d45bc4a-85b3-4e0b-9a75-28a3780e5965'	System	12 Oct 2020 19:30:39
User entered 'None (0)'	System	12 Oct 2020 19:30:39

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:17:05

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-12T12:30:24', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '6d45bc4a-85b3-4e0b-9a75-28a3780e5965'	System	12 Oct 2020 19:30:39
User entered 'None (0)'	System	12 Oct 2020 19:30:39

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-12T12:30:31', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '6d45bc4a-85b3-4e0b-9a75-28a3780e5965'	System	12 Oct 2020 19:30:39
User entered 'No (N)'	System	12 Oct 2020 19:30:39

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:17:05

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-12T12:30:37', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '6d45bc4a-85b3-4e0b-9a75-28a3780e5965'	System	12 Oct 2020 19:30:39
User entered '12 Oct 2020 12:30'	System	12 Oct 2020 19:30:39

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 5'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:17:05

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-13T13:06:11', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'de3a067a-d4ff-42f3-8ecc-f7f0d52c79e2'	System	13 Oct 2020 20:06:46
User entered 'None (0)'	System	13 Oct 2020 20:06:46

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:17:05

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-13T13:06:14', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'de3a067a-d4ff-42f3-8ecc-f7f0d52c79e2'	System	13 Oct 2020 20:06:46
User entered 'None (0)'	System	13 Oct 2020 20:06:46

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:17:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-13T13:06:18', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'de3a067a-d4ff-42f3-8ecc-f7f0d52c79e2'	System	13 Oct 2020 20:06:46
User entered 'None (0)'	System	13 Oct 2020 20:06:46

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:17:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-13T13:06:24', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'de3a067a-d4ff-42f3-8ecc-f7f0d52c79e2'	System	13 Oct 2020 20:06:46
User entered 'None (0)'	System	13 Oct 2020 20:06:46

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:17:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-13T13:06:27', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'de3a067a-d4ff-42f3-8ecc-f7f0d52c79e2'	System	13 Oct 2020 20:06:46
User entered 'None (0)'	System	13 Oct 2020 20:06:46

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:17:05

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-13T13:06:31', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'de3a067a-d4ff-42f3-8ecc-f7f0d52c79e2'	System	13 Oct 2020 20:06:46
User entered 'None (0)'	System	13 Oct 2020 20:06:46

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-13T13:06:37', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'de3a067a-d4ff-42f3-8ecc-f7f0d52c79e2'	System	13 Oct 2020 20:06:46
User entered 'No (N)'	System	13 Oct 2020 20:06:46

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:17:05

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-13T13:06:40', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'de3a067a-d4ff-42f3-8ecc-f7f0d52c79e2'	System	13 Oct 2020 20:06:46
User entered '13 Oct 2020 13:06'	System	13 Oct 2020 20:06:46

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 6'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:17:05

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-14T12:36:49', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'c32e7830-2578-4020-b9ac-f8c618d2ec74'	System	14 Oct 2020 19:37:30
User entered 'None (0)'	System	14 Oct 2020 19:37:30

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:17:05

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-14T12:36:52', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'c32e7830-2578-4020-b9ac-f8c618d2ec74'	System	14 Oct 2020 19:37:30
User entered 'None (0)'	System	14 Oct 2020 19:37:30

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:17:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-14T12:36:58', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'c32e7830-2578-4020-b9ac-f8c618d2ec74'	System	14 Oct 2020 19:37:30
User entered 'None (0)'	System	14 Oct 2020 19:37:30

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:17:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-14T12:37:04', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'c32e7830-2578-4020-b9ac-f8c618d2ec74'	System	14 Oct 2020 19:37:30
User entered 'None (0)'	System	14 Oct 2020 19:37:30

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:17:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-14T12:37:11', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'c32e7830-2578-4020-b9ac-f8c618d2ec74'	System	14 Oct 2020 19:37:30
User entered 'None (0)'	System	14 Oct 2020 19:37:30

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:17:05

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-14T12:37:14', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'c32e7830-2578-4020-b9ac-f8c618d2ec74'	System	14 Oct 2020 19:37:30
User entered 'None (0)'	System	14 Oct 2020 19:37:30

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-14T12:37:20', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'c32e7830-2578-4020-b9ac-f8c618d2ec74'	System	14 Oct 2020 19:37:30
User entered 'No (N)'	System	14 Oct 2020 19:37:30

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:17:05

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-14T12:37:26', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'c32e7830-2578-4020-b9ac-f8c618d2ec74'	System	14 Oct 2020 19:37:30
User entered '14 Oct 2020 12:37'	System	14 Oct 2020 19:37:30

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 7'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:17:05

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-15T17:02:06', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5841fae0-53d6-4e9e-8dda-58228ea764b0'	System	16 Oct 2020 00:02:40
User entered 'None (0)'	System	16 Oct 2020 00:02:40

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:17:05

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-15T17:02:10', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5841fae0-53d6-4e9e-8dda-58228ea764b0'	System	16 Oct 2020 00:02:40
User entered 'None (0)'	System	16 Oct 2020 00:02:40

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:17:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-15T17:02:13', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5841fae0-53d6-4e9e-8dda-58228ea764b0'	System	16 Oct 2020 00:02:40
User entered 'None (0)'	System	16 Oct 2020 00:02:40

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:17:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-15T17:02:19', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5841fae0-53d6-4e9e-8dda-58228ea764b0'	System	16 Oct 2020 00:02:40
User entered 'None (0)'	System	16 Oct 2020 00:02:40

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:17:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-15T17:02:22', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5841fae0-53d6-4e9e-8dda-58228ea764b0'	System	16 Oct 2020 00:02:40
User entered 'None (0)'	System	16 Oct 2020 00:02:40

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:17:05

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-15T17:02:25', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5841fae0-53d6-4e9e-8dda-58228ea764b0'	System	16 Oct 2020 00:02:40
User entered 'None (0)'	System	16 Oct 2020 00:02:40

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-15T17:02:31', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5841fae0-53d6-4e9e-8dda-58228ea764b0'	System	16 Oct 2020 00:02:40
User entered 'No (N)'	System	16 Oct 2020 00:02:40

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:17:05

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-15T17:02:35', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5841fae0-53d6-4e9e-8dda-58228ea764b0'	System	16 Oct 2020 00:02:40
User entered '15 Oct 2020 17:02'	System	16 Oct 2020 00:02:40

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

US3792094

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:17:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	19 Oct 2020 20:14:28

US3792094

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '19 Oct 2020'	Ann Marie Milliken	19 Oct 2020 20:14:28
	(b) (4)	

US3792094

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:17:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken (b) (4)	19 Oct 2020 20:14:28

US3792094

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:17:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Ann Marie Milliken (b) (4)	19 Oct 2020 20:14:28

US3792094

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	19 Oct 2020 20:14:34

US3792094

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:17:05

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 20:14:34

US3792094

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:17:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	23 Oct 2020 20:21:35

US3792094

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Ann Marie Milliken	23 Oct 2020 20:21:35
	(b) (4)	

US3792094

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:17:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken (b) (4)	23 Oct 2020 20:21:35

US3792094

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:17:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Ann Marie Milliken (b) (4)	23 Oct 2020 20:21:35

US3792094

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ann Marie Milliken	23 Oct 2020 20:21:41
	(b) (4)	

US3792094

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:17:05

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 20:21:41

US3792094

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:17:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ann Marie Milliken	30 Oct 2020 19:05:32
	(b) (4)	

US3792094

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '30 Oct 2020'	Ann Marie Milliken	30 Oct 2020 19:05:32
	(b) (4)	

US3792094

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:17:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken (b) (4)	30 Oct 2020 19:05:32

US3792094

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:17:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Ann Marie Milliken (b) (4)	30 Oct 2020 19:05:32

US3792094

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	30 Oct 2020 19:05:37

US3792094

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:17:05

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 19:05:37

US3792094

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:17:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:12:11
	(b) (4)	

US3792094

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '6 Nov 2020'	Norma Frederick (b) (4)	06 Nov 2020 20:12:11
	(b) (4)	

US3792094

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4)	06 Nov 2020 20:12:11
	(b) (4)	

US3792094

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:17:05

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	06 Nov 2020 20:12:11

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:17:05

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:38:08

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:17:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:38:08

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:17:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '6 Nov 2020'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:38:08

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '11:39'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:38:08

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '6 Nov 2020 11:39'	System	13 Nov 2020 18:38:08

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:17:05

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.2' F	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:38:08

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:17:05

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:38:08

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:17:05

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:38:08

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:17:05

Pulse (xxx)

Audit	User	Time (GMT)
User entered '65'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:38:08

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:17:05

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Nov 2020 18:38:08

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '14'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:38:08

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:17:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Nov 2020 18:38:08

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:17:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '130'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:38:08

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:17:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Nov 2020 18:38:08

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:17:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '80'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:38:08

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:17:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Nov 2020 18:38:08

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:17:05

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:38:08

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:17:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:38:08

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:17:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '6 Nov 2020'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:38:08

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '13:09'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:38:08

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '6 Nov 2020 13:09'	System	13 Nov 2020 18:38:08

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:17:05

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.2' F	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:38:08

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:17:05

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:38:08

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:17:05

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:38:08

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:17:05

Pulse (xxx)

Audit	User	Time (GMT)
User entered '64'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:38:08

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:17:05

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Nov 2020 18:38:08

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '16'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:38:08

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:17:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Nov 2020 18:38:08

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:17:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '107'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:38:08

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:17:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Nov 2020 18:38:08

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:17:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '79'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:38:08

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:17:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Nov 2020 18:38:08

US3792094

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:17:05

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:31:31
	(b) (4)	

US3792094

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:17:05

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '6 Nov 2020'	Norma Frederick (b) (4)	06 Nov 2020 20:31:31
	(b) (4)	

US3792094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:17:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:11:52

US3792094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:17:05

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 20:11:52
	(b) (4)	

US3792094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 20:11:52

US3792094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:17:05

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	06 Nov 2020 20:11:52

US3792094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:17:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '6 Nov 2020'	Norma Frederick (b) (4)	06 Nov 2020 20:11:52
	(b) (4)	

US3792094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '12:19'	Norma Frederick (b) (4)	06 Nov 2020 20:11:52
	(b) (4)	

US3792094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '6 Nov 2020 12:19'	System	06 Nov 2020 20:11:52

US3792094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:17:05

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Norma Frederick (b) (4)	06 Nov 2020 20:11:52

US3792094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	06 Nov 2020 20:11:52

US3792094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:17:05

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	06 Nov 2020 20:11:52

US3792094

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:17:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:38:35

US3792094

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:17:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '6 Nov 2020'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:38:35

US3792094

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:17:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '11:43'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:38:35

US3792094

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '6 Nov 2020 11:43'	System	13 Nov 2020 18:38:35

US3792094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:17:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '6 Nov 2020'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:38:52

US3792094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:17:05

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:38:52

US3792094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:17:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:38:52

US3792094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:17:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '11:50'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:38:52

US3792094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered '6 Nov 2020 11:50'	System	13 Nov 2020 18:38:52

US3792094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:17:05

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:38:52

US3792094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:17:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:38:52

US3792094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:17:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:38:52

US3792094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 18:38:52

US3792094

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:12:22
	(b) (4)	

US3792094

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:17:05

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 20:12:22

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T13:12:09', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '4c90c9b0-ad72-4122-a238-c0451058d3f3'	System	06 Nov 2020 20:13:09
User entered 'Yes (Y)'	System	06 Nov 2020 20:13:09

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T13:12:51', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '4c90c9b0-ad72-4122-a238-c0451058d3f3'	System	06 Nov 2020 20:13:09
User entered '98.2'	System	06 Nov 2020 20:13:09

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T13:12:56', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '4c90c9b0-ad72-4122-a238-c0451058d3f3'	System	06 Nov 2020 20:13:09
User entered 'No (N)'	System	06 Nov 2020 20:13:09

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T13:13:03', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '4c90c9b0-ad72-4122-a238-c0451058d3f3'	System	06 Nov 2020 20:13:09
User entered '06 Nov 2020 13:13'	System	06 Nov 2020 20:13:09

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Nov 2020 12:39'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Nov 2020 15:09'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 1, after vaccination (at home)'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T18:09:59', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'e882e192-ca5e-4f6f-8ef0-fac2fd21a446'	System	07 Nov 2020 01:10:51
User entered 'Yes (Y)'	System	07 Nov 2020 01:10:51

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T18:10:35', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'e882e192-ca5e-4f6f-8ef0-fac2fd21a446'	System	07 Nov 2020 01:10:51
User entered '95.4'	System	07 Nov 2020 01:10:51

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T18:10:40', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'e882e192-ca5e-4f6f-8ef0-fac2fd21a446'	System	07 Nov 2020 01:10:51
User entered 'No (N)'	System	07 Nov 2020 01:10:51

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T18:10:47', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'e882e192-ca5e-4f6f-8ef0-fac2fd21a446'	System	07 Nov 2020 01:10:51
User entered '06 Nov 2020 18:10'	System	07 Nov 2020 01:10:51

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Nov 2020 16:04'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 2'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:17:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-07T21:09:34', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '653d2312-020a-4e08-9b31-9e455b317f6e'	System	08 Nov 2020 04:09:55
User entered 'Yes (Y)'	System	08 Nov 2020 04:09:55

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:17:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-07T21:09:44', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '653d2312-020a-4e08-9b31-9e455b317f6e'	System	08 Nov 2020 04:09:55
User entered '98.5'	System	08 Nov 2020 04:09:55

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-07T21:09:47', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '653d2312-020a-4e08-9b31-9e455b317f6e'	System	08 Nov 2020 04:09:55
User entered 'No (N)'	System	08 Nov 2020 04:09:55

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:17:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-07T21:09:51', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '653d2312-020a-4e08-9b31-9e455b317f6e'	System	08 Nov 2020 04:09:55
User entered '07 Nov 2020 21:09'	System	08 Nov 2020 04:09:55

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Nov 2020 12:00'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 3'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:17:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-08T19:54:58', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8ee65e23-24d1-43fd-ab5b-446211b45a29'	System	09 Nov 2020 02:55:58
User entered 'Yes (Y)'	System	09 Nov 2020 02:55:58

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:17:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-08T19:55:35', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8ee65e23-24d1-43fd-ab5b-446211b45a29'	System	09 Nov 2020 02:55:58
User entered '98.0'	System	09 Nov 2020 02:55:58

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-08T19:55:48', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8ee65e23-24d1-43fd-ab5b-446211b45a29'	System	09 Nov 2020 02:55:58
User entered 'No (N)'	System	09 Nov 2020 02:55:58

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:17:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-08T19:55:55', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8ee65e23-24d1-43fd-ab5b-446211b45a29'	System	09 Nov 2020 02:55:58
User entered '08 Nov 2020 19:55'	System	09 Nov 2020 02:55:58

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Nov 2020 12:00'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 4'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:17:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-09T23:49:12', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '24113f57-ddd0-4e2b-9705-37eb201c240c'	System	10 Nov 2020 06:50:05
User entered 'Yes (Y)'	System	10 Nov 2020 06:50:05

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:17:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-09T23:49:38', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '24113f57-ddd0-4e2b-9705-37eb201c240c'	System	10 Nov 2020 06:50:05
User entered '97.5'	System	10 Nov 2020 06:50:05

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-09T23:49:53', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '24113f57-ddd0-4e2b-9705-37eb201c240c'	System	10 Nov 2020 06:50:05
User entered 'No (N)'	System	10 Nov 2020 06:50:05

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:17:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-09T23:50:02', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '24113f57-ddd0-4e2b-9705-37eb201c240c'	System	10 Nov 2020 06:50:05
User entered '09 Nov 2020 23:50'	System	10 Nov 2020 06:50:05

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Nov 2020 12:00'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 5'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:17:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-10T23:56:58', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '7724e20d-4650-4cef-b0c3-16bcf394faf0'	System	11 Nov 2020 06:57:56
User entered 'Yes (Y)'	System	11 Nov 2020 06:57:56

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:17:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-10T23:57:42', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '7724e20d-4650-4cef-b0c3-16bcf394faf0'	System	11 Nov 2020 06:57:56
User entered '96.8'	System	11 Nov 2020 06:57:56

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-10T23:57:46', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '7724e20d-4650-4cef-b0c3-16bcf394faf0'	System	11 Nov 2020 06:57:56
User entered 'No (N)'	System	11 Nov 2020 06:57:56

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:17:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-10T23:57:52', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '7724e20d-4650-4cef-b0c3-16bcf394faf0'	System	11 Nov 2020 06:57:56
User entered '10 Nov 2020 23:57'	System	11 Nov 2020 06:57:56

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Nov 2020 12:00'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 6'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:17:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-11T20:59:56', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '47800afc-35a8-4b5e-b5b4-1f1abb89d726'	System	12 Nov 2020 04:00:19
User entered 'Yes (Y)'	System	12 Nov 2020 04:00:19

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:17:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-11T21:00:03', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '47800afc-35a8-4b5e-b5b4-1f1abb89d726'	System	12 Nov 2020 04:00:19
User entered '98.2'	System	12 Nov 2020 04:00:19

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-11T21:00:06', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '47800afc-35a8-4b5e-b5b4-1f1abb89d726'	System	12 Nov 2020 04:00:19
User entered 'No (N)'	System	12 Nov 2020 04:00:19

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:17:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-11T21:00:15', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '47800afc-35a8-4b5e-b5b4-1f1abb89d726'	System	12 Nov 2020 04:00:19
User entered '11 Nov 2020 21:00'	System	12 Nov 2020 04:00:19

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020 12:00'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 7'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:17:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-12T19:38:59', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'fb2fe3c2-4d42-426a-a135-32dc69d40460'	System	13 Nov 2020 02:39:18
User entered 'Yes (Y)'	System	13 Nov 2020 02:39:18

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:17:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-12T19:39:06', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'fb2fe3c2-4d42-426a-a135-32dc69d40460'	System	13 Nov 2020 02:39:18
User entered '95.4'	System	13 Nov 2020 02:39:18

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-12T19:39:09', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'fb2fe3c2-4d42-426a-a135-32dc69d40460'	System	13 Nov 2020 02:39:18
User entered 'No (N)'	System	13 Nov 2020 02:39:18

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:17:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-12T19:39:14', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'fb2fe3c2-4d42-426a-a135-32dc69d40460'	System	13 Nov 2020 02:39:18
User entered '12 Nov 2020 19:39'	System	13 Nov 2020 02:39:18

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Nov 2020 12:00'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T13:13:25', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '79fe30e9-644c-4092-9565-94a32fd0c9b6'	System	06 Nov 2020 20:13:57
User entered 'None (1)'	System	06 Nov 2020 20:13:57

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T13:13:29', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '79fe30e9-644c-4092-9565-94a32fd0c9b6'	System	06 Nov 2020 20:13:57
User entered 'No (N)'	System	06 Nov 2020 20:13:57

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T13:13:38', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '79fe30e9-644c-4092-9565-94a32fd0c9b6'	System	06 Nov 2020 20:13:57
User entered 'No (N)'	System	06 Nov 2020 20:13:57

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T13:13:48', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '79fe30e9-644c-4092-9565-94a32fd0c9b6'	System	06 Nov 2020 20:13:57
User entered 'None (1)'	System	06 Nov 2020 20:13:57

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T13:13:53', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '79fe30e9-644c-4092-9565-94a32fd0c9b6'	System	06 Nov 2020 20:13:57
User entered '06 Nov 2020 13:13'	System	06 Nov 2020 20:13:57

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Nov 2020 12:39'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Nov 2020 15:09'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 1, after vaccination (at home)'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T18:11:04', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'ea99734e-22f5-468e-9042-f68dde4da310'	System	07 Nov 2020 01:11:33
User entered 'None (1)'	System	07 Nov 2020 01:11:33

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T18:11:07', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'ea99734e-22f5-468e-9042-f68dde4da310'	System	07 Nov 2020 01:11:33
User entered 'No (N)'	System	07 Nov 2020 01:11:33

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T18:11:13', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'ea99734e-22f5-468e-9042-f68dde4da310'	System	07 Nov 2020 01:11:33
User entered 'No (N)'	System	07 Nov 2020 01:11:33

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T18:11:19', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'ea99734e-22f5-468e-9042-f68dde4da310'	System	07 Nov 2020 01:11:33
User entered 'None (1)'	System	07 Nov 2020 01:11:33

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T18:11:29', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'ea99734e-22f5-468e-9042-f68dde4da310'	System	07 Nov 2020 01:11:33
User entered '06 Nov 2020 18:11'	System	07 Nov 2020 01:11:33

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Nov 2020 16:04'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 2'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:17:05

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-07T21:10:04', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '0d5cb598-1a31-47c4-b754-e05c93349622'	System	08 Nov 2020 04:10:26
User entered 'None (1)'	System	08 Nov 2020 04:10:26

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:17:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-07T21:10:07', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '0d5cb598-1a31-47c4-b754-e05c93349622'	System	08 Nov 2020 04:10:26
User entered 'No (N)'	System	08 Nov 2020 04:10:26

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-07T21:10:10', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '0d5cb598-1a31-47c4-b754-e05c93349622'	System	08 Nov 2020 04:10:26
User entered 'No (N)'	System	08 Nov 2020 04:10:26

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:17:05

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-07T21:10:14', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '0d5cb598-1a31-47c4-b754-e05c93349622'	System	08 Nov 2020 04:10:26
User entered 'None (1)'	System	08 Nov 2020 04:10:26

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:17:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-07T21:10:22', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '0d5cb598-1a31-47c4-b754-e05c93349622'	System	08 Nov 2020 04:10:26
User entered '07 Nov 2020 21:10'	System	08 Nov 2020 04:10:26

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Nov 2020 12:00'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 3'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:17:05

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-08T19:56:02', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'b0bc647b-b67f-4f91-8536-958b9895f66f'	System	09 Nov 2020 02:56:24
User entered 'None (1)'	System	09 Nov 2020 02:56:24

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:17:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-08T19:56:05', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'b0bc647b-b67f-4f91-8536-958b9895f66f'	System	09 Nov 2020 02:56:24
User entered 'No (N)'	System	09 Nov 2020 02:56:24

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-08T19:56:10', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'b0bc647b-b67f-4f91-8536-958b9895f66f'	System	09 Nov 2020 02:56:24
User entered 'No (N)'	System	09 Nov 2020 02:56:24

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:17:05

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-08T19:56:14', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'b0bc647b-b67f-4f91-8536-958b9895f66f'	System	09 Nov 2020 02:56:24
User entered 'None (1)'	System	09 Nov 2020 02:56:24

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:17:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-08T19:56:19', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'b0bc647b-b67f-4f91-8536-958b9895f66f'	System	09 Nov 2020 02:56:24
User entered '08 Nov 2020 19:56'	System	09 Nov 2020 02:56:24

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Nov 2020 12:00'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 4'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:17:05

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-09T23:50:07', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '1f33b3fc-df88-43fe-af7e-c38b163c85ec'	System	10 Nov 2020 06:50:28
User entered 'None (1)'	System	10 Nov 2020 06:50:28

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:17:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-09T23:50:12', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '1f33b3fc-df88-43fe-af7e-c38b163c85ec'	System	10 Nov 2020 06:50:28
User entered 'No (N)'	System	10 Nov 2020 06:50:28

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-09T23:50:16', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '1f33b3fc-df88-43fe-af7e-c38b163c85ec'	System	10 Nov 2020 06:50:28
User entered 'No (N)'	System	10 Nov 2020 06:50:28

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:17:05

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-09T23:50:18', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '1f33b3fc-df88-43fe-af7e-c38b163c85ec'	System	10 Nov 2020 06:50:28
User entered 'None (1)'	System	10 Nov 2020 06:50:28

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:17:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-09T23:50:22', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '1f33b3fc-df88-43fe-af7e-c38b163c85ec'	System	10 Nov 2020 06:50:28
User entered '09 Nov 2020 23:50'	System	10 Nov 2020 06:50:28

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Nov 2020 12:00'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 5'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:17:05

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-10T23:57:57', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '1f14154c-0936-4992-8300-f738a133f4f7'	System	11 Nov 2020 06:58:13
User entered 'None (1)'	System	11 Nov 2020 06:58:13

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:17:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-10T23:58:00', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '1f14154c-0936-4992-8300-f738a133f4f7'	System	11 Nov 2020 06:58:13
User entered 'No (N)'	System	11 Nov 2020 06:58:13

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-10T23:58:03', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '1f14154c-0936-4992-8300-f738a133f4f7'	System	11 Nov 2020 06:58:13
User entered 'No (N)'	System	11 Nov 2020 06:58:13

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:17:05

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-10T23:58:05', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '1f14154c-0936-4992-8300-f738a133f4f7'	System	11 Nov 2020 06:58:13
User entered 'None (1)'	System	11 Nov 2020 06:58:13

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:17:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-10T23:58:09', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '1f14154c-0936-4992-8300-f738a133f4f7'	System	11 Nov 2020 06:58:13
User entered '10 Nov 2020 23:58'	System	11 Nov 2020 06:58:13

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Nov 2020 12:00'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 6'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:17:05

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-11T21:00:21', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '42718bbf-97b1-423d-bd7a-7e9e53d27cf0'	System	12 Nov 2020 04:00:45
User entered 'None (1)'	System	12 Nov 2020 04:00:45

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:17:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-11T21:00:24', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '42718bbf-97b1-423d-bd7a-7e9e53d27cf0'	System	12 Nov 2020 04:00:45
User entered 'No (N)'	System	12 Nov 2020 04:00:45

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:17:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-11T21:00:28', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '42718bbf-97b1-423d-bd7a-7e9e53d27cf0'	System	12 Nov 2020 04:00:45
User entered 'No (N)'	System	12 Nov 2020 04:00:45

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:17:05

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-11T21:00:31', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '42718bbf-97b1-423d-bd7a-7e9e53d27cf0'	System	12 Nov 2020 04:00:45
User entered 'None (1)'	System	12 Nov 2020 04:00:45

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:17:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-11T21:00:40', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '42718bbf-97b1-423d-bd7a-7e9e53d27cf0'	System	12 Nov 2020 04:00:45
User entered '11 Nov 2020 21:00'	System	12 Nov 2020 04:00:45

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020 12:00'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 7'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:17:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-12T19:39:26', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '02d93d7e-ad1a-41d3-8617-fb21a02d2ba3'	System	13 Nov 2020 02:39:43
User entered 'None (1)'	System	13 Nov 2020 02:39:43

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:17:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-12T19:39:29', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '02d93d7e-ad1a-41d3-8617-fb21a02d2ba3'	System	13 Nov 2020 02:39:43
User entered 'No (N)'	System	13 Nov 2020 02:39:43

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:17:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-12T19:39:32', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '02d93d7e-ad1a-41d3-8617-fb21a02d2ba3'	System	13 Nov 2020 02:39:43
User entered 'No (N)'	System	13 Nov 2020 02:39:43

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:17:05

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-12T19:39:35', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '02d93d7e-ad1a-41d3-8617-fb21a02d2ba3'	System	13 Nov 2020 02:39:43
User entered 'None (1)'	System	13 Nov 2020 02:39:43

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:17:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-12T19:39:39', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '02d93d7e-ad1a-41d3-8617-fb21a02d2ba3'	System	13 Nov 2020 02:39:43
User entered '12 Nov 2020 19:39'	System	13 Nov 2020 02:39:43

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Nov 2020 12:00'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T13:13:58', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f454887d-2f61-4025-9862-bf848f2819cb'	System	06 Nov 2020 20:14:24
User entered 'None (0)'	System	06 Nov 2020 20:14:24

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T13:14:02', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f454887d-2f61-4025-9862-bf848f2819cb'	System	06 Nov 2020 20:14:24
User entered 'None (0)'	System	06 Nov 2020 20:14:24

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T13:14:07', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f454887d-2f61-4025-9862-bf848f2819cb'	System	06 Nov 2020 20:14:24
User entered 'None (0)'	System	06 Nov 2020 20:14:24

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T13:14:09', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f454887d-2f61-4025-9862-bf848f2819cb'	System	06 Nov 2020 20:14:24
User entered 'None (0)'	System	06 Nov 2020 20:14:24

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T13:14:11', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f454887d-2f61-4025-9862-bf848f2819cb'	System	06 Nov 2020 20:14:24
User entered 'None (0)'	System	06 Nov 2020 20:14:24

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T13:14:13', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f454887d-2f61-4025-9862-bf848f2819cb'	System	06 Nov 2020 20:14:24
User entered 'None (0)'	System	06 Nov 2020 20:14:24

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T13:14:15', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f454887d-2f61-4025-9862-bf848f2819cb'	System	06 Nov 2020 20:14:24
User entered 'No (N)'	System	06 Nov 2020 20:14:24

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T13:14:20', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f454887d-2f61-4025-9862-bf848f2819cb'	System	06 Nov 2020 20:14:24
User entered '06 Nov 2020 13:14'	System	06 Nov 2020 20:14:24

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Nov 2020 12:39'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Nov 2020 15:09'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 1, after vaccination (at home)'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T18:12:26', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8165700f-b3e4-405c-a862-f198d9d502e4'	System	07 Nov 2020 01:13:02
User entered 'None (0)'	System	07 Nov 2020 01:13:02

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T18:12:29', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8165700f-b3e4-405c-a862-f198d9d502e4'	System	07 Nov 2020 01:13:02
User entered 'None (0)'	System	07 Nov 2020 01:13:02

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T18:12:35', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8165700f-b3e4-405c-a862-f198d9d502e4'	System	07 Nov 2020 01:13:02
User entered 'None (0)'	System	07 Nov 2020 01:13:02

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T18:12:41', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8165700f-b3e4-405c-a862-f198d9d502e4'	System	07 Nov 2020 01:13:02
User entered 'None (0)'	System	07 Nov 2020 01:13:02

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T18:12:43', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8165700f-b3e4-405c-a862-f198d9d502e4'	System	07 Nov 2020 01:13:02
User entered 'None (0)'	System	07 Nov 2020 01:13:02

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T18:12:47', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8165700f-b3e4-405c-a862-f198d9d502e4'	System	07 Nov 2020 01:13:02
User entered 'None (0)'	System	07 Nov 2020 01:13:02

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T18:12:53', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8165700f-b3e4-405c-a862-f198d9d502e4'	System	07 Nov 2020 01:13:02
User entered 'No (N)'	System	07 Nov 2020 01:13:02

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T18:12:58', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8165700f-b3e4-405c-a862-f198d9d502e4'	System	07 Nov 2020 01:13:02
User entered '06 Nov 2020 18:12'	System	07 Nov 2020 01:13:02

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Nov 2020 16:04'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:17:05

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 2'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:17:05

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-07T21:10:27', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '93f0efd1-9bb0-4923-aa7f-36a2fef00b68'	System	08 Nov 2020 04:11:08
User entered 'None (0)'	System	08 Nov 2020 04:11:08

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:17:05

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-07T21:10:29', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '93f0efd1-9bb0-4923-aa7f-36a2fef00b68'	System	08 Nov 2020 04:11:08
User entered 'None (0)'	System	08 Nov 2020 04:11:08

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:17:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-07T21:10:32', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '93f0efd1-9bb0-4923-aa7f-36a2fef00b68'	System	08 Nov 2020 04:11:08
User entered 'None (0)'	System	08 Nov 2020 04:11:08

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:17:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-07T21:10:34', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '93f0efd1-9bb0-4923-aa7f-36a2fef00b68'	System	08 Nov 2020 04:11:08
User entered 'None (0)'	System	08 Nov 2020 04:11:08

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:17:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-07T21:10:36', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '93f0efd1-9bb0-4923-aa7f-36a2fef00b68'	System	08 Nov 2020 04:11:08
User entered 'None (0)'	System	08 Nov 2020 04:11:08

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:17:05

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-07T21:10:39', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '93f0efd1-9bb0-4923-aa7f-36a2fef00b68'	System	08 Nov 2020 04:11:08
User entered 'None (0)'	System	08 Nov 2020 04:11:08

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:17:05

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-07T21:10:54', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '93f0efd1-9bb0-4923-aa7f-36a2fef00b68'	System	08 Nov 2020 04:11:08
User entered 'No (N)'	System	08 Nov 2020 04:11:08

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:17:05

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-07T21:11:03', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '93f0efd1-9bb0-4923-aa7f-36a2fef00b68'	System	08 Nov 2020 04:11:08
User entered '07 Nov 2020 21:11'	System	08 Nov 2020 04:11:08

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Nov 2020 12:00'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 3'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:17:05

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-08T19:56:24', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '2f17c792-7c78-4541-b047-f62350554d8e'	System	09 Nov 2020 02:56:54
User entered 'None (0)'	System	09 Nov 2020 02:56:54

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:17:05

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-08T19:56:27', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '2f17c792-7c78-4541-b047-f62350554d8e'	System	09 Nov 2020 02:56:54
User entered 'None (0)'	System	09 Nov 2020 02:56:54

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:17:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-08T19:56:29', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '2f17c792-7c78-4541-b047-f62350554d8e'	System	09 Nov 2020 02:56:54
User entered 'None (0)'	System	09 Nov 2020 02:56:54

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:17:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-08T19:56:31', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '2f17c792-7c78-4541-b047-f62350554d8e'	System	09 Nov 2020 02:56:54
User entered 'None (0)'	System	09 Nov 2020 02:56:54

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:17:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-08T19:56:34', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '2f17c792-7c78-4541-b047-f62350554d8e'	System	09 Nov 2020 02:56:54
User entered 'None (0)'	System	09 Nov 2020 02:56:54

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:17:05

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-08T19:56:36', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '2f17c792-7c78-4541-b047-f62350554d8e'	System	09 Nov 2020 02:56:54
User entered 'None (0)'	System	09 Nov 2020 02:56:54

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:17:05

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-08T19:56:43', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '2f17c792-7c78-4541-b047-f62350554d8e'	System	09 Nov 2020 02:56:54
User entered 'No (N)'	System	09 Nov 2020 02:56:54

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:17:05

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-08T19:56:49', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '2f17c792-7c78-4541-b047-f62350554d8e'	System	09 Nov 2020 02:56:54
User entered '08 Nov 2020 19:56'	System	09 Nov 2020 02:56:54

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Nov 2020 12:00'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 4'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:17:05

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-09T23:50:26', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '148fb8e5-5c9c-4e1f-bc58-b13ba10fde11'	System	10 Nov 2020 06:50:59
User entered 'None (0)'	System	10 Nov 2020 06:50:59

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:17:05

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-09T23:50:30', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '148fb8e5-5c9c-4e1f-bc58-b13ba10fde11'	System	10 Nov 2020 06:50:59
User entered 'None (0)'	System	10 Nov 2020 06:50:59

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:17:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-09T23:50:32', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '148fb8e5-5c9c-4e1f-bc58-b13ba10fde11'	System	10 Nov 2020 06:50:59
User entered 'None (0)'	System	10 Nov 2020 06:50:59

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:17:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-09T23:50:35', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '148fb8e5-5c9c-4e1f-bc58-b13ba10fde11'	System	10 Nov 2020 06:50:59
User entered 'None (0)'	System	10 Nov 2020 06:50:59

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:17:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-09T23:50:37', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '148fb8e5-5c9c-4e1f-bc58-b13ba10fde11'	System	10 Nov 2020 06:50:59
User entered 'None (0)'	System	10 Nov 2020 06:50:59

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:17:05

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-09T23:50:39', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '148fb8e5-5c9c-4e1f-bc58-b13ba10fde11'	System	10 Nov 2020 06:50:59
User entered 'None (0)'	System	10 Nov 2020 06:50:59

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:17:05

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-09T23:50:47', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '148fb8e5-5c9c-4e1f-bc58-b13ba10fde11'	System	10 Nov 2020 06:50:59
User entered 'No (N)'	System	10 Nov 2020 06:50:59

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:17:05

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-09T23:50:55', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '148fb8e5-5c9c-4e1f-bc58-b13ba10fde11'	System	10 Nov 2020 06:50:59
User entered '09 Nov 2020 23:50'	System	10 Nov 2020 06:50:59

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Nov 2020 12:00'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 5'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:17:05

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-10T23:58:13', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '09bfa454-840c-4728-8f46-fbb8d2a59315'	System	11 Nov 2020 06:58:34
User entered 'None (0)'	System	11 Nov 2020 06:58:34

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:17:05

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-10T23:58:16', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '09bfa454-840c-4728-8f46-fbb8d2a59315'	System	11 Nov 2020 06:58:34
User entered 'None (0)'	System	11 Nov 2020 06:58:34

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:17:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-10T23:58:19', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '09bfa454-840c-4728-8f46-fbb8d2a59315'	System	11 Nov 2020 06:58:34
User entered 'None (0)'	System	11 Nov 2020 06:58:34

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:17:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-10T23:58:21', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '09bfa454-840c-4728-8f46-fbb8d2a59315'	System	11 Nov 2020 06:58:34
User entered 'None (0)'	System	11 Nov 2020 06:58:34

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:17:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-10T23:58:23', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '09bfa454-840c-4728-8f46-fbb8d2a59315'	System	11 Nov 2020 06:58:34
User entered 'None (0)'	System	11 Nov 2020 06:58:34

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:17:05

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-10T23:58:25', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '09bfa454-840c-4728-8f46-fbb8d2a59315'	System	11 Nov 2020 06:58:34
User entered 'None (0)'	System	11 Nov 2020 06:58:34

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:17:05

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-10T23:58:28', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '09bfa454-840c-4728-8f46-fbb8d2a59315'	System	11 Nov 2020 06:58:34
User entered 'No (N)'	System	11 Nov 2020 06:58:34

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:17:05

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-10T23:58:32', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '09bfa454-840c-4728-8f46-fbb8d2a59315'	System	11 Nov 2020 06:58:34
User entered '10 Nov 2020 23:58'	System	11 Nov 2020 06:58:34

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Nov 2020 12:00'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 6'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:17:05

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-11T21:00:45', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'b47d646e-2a19-4eb1-9175-3f5bfe80fcc2'	System	12 Nov 2020 04:01:13
User entered 'None (0)'	System	12 Nov 2020 04:01:13

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:17:05

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-11T21:00:48', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'b47d646e-2a19-4eb1-9175-3f5bfe80fcc2'	System	12 Nov 2020 04:01:13
User entered 'None (0)'	System	12 Nov 2020 04:01:13

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:17:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-11T21:00:51', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'b47d646e-2a19-4eb1-9175-3f5bfe80fcc2'	System	12 Nov 2020 04:01:13
User entered 'None (0)'	System	12 Nov 2020 04:01:13

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:17:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-11T21:00:53', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'b47d646e-2a19-4eb1-9175-3f5bfe80fcc2'	System	12 Nov 2020 04:01:13
User entered 'None (0)'	System	12 Nov 2020 04:01:13

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:17:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-11T21:00:56', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'b47d646e-2a19-4eb1-9175-3f5bfe80fcc2'	System	12 Nov 2020 04:01:13
User entered 'None (0)'	System	12 Nov 2020 04:01:13

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:17:05

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-11T21:00:59', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'b47d646e-2a19-4eb1-9175-3f5bfe80fcc2'	System	12 Nov 2020 04:01:13
User entered 'None (0)'	System	12 Nov 2020 04:01:13

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:17:05

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-11T21:01:05', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'b47d646e-2a19-4eb1-9175-3f5bfe80fcc2'	System	12 Nov 2020 04:01:13
User entered 'No (N)'	System	12 Nov 2020 04:01:13

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:17:05

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-11T21:01:10', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'b47d646e-2a19-4eb1-9175-3f5bfe80fcc2'	System	12 Nov 2020 04:01:13
User entered '11 Nov 2020 21:01'	System	12 Nov 2020 04:01:13

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020 12:00'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 7'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:17:05

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-12T19:39:43', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f84a57cd-394d-43ad-9f39-48ea46bcc20d'	System	13 Nov 2020 02:40:12
User entered 'None (0)'	System	13 Nov 2020 02:40:12

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:17:05

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-12T19:39:45', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f84a57cd-394d-43ad-9f39-48ea46bcc20d'	System	13 Nov 2020 02:40:12
User entered 'None (0)'	System	13 Nov 2020 02:40:12

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:17:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-12T19:39:48', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f84a57cd-394d-43ad-9f39-48ea46bcc20d'	System	13 Nov 2020 02:40:12
User entered 'None (0)'	System	13 Nov 2020 02:40:12

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:17:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-12T19:39:51', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f84a57cd-394d-43ad-9f39-48ea46bcc20d'	System	13 Nov 2020 02:40:12
User entered 'None (0)'	System	13 Nov 2020 02:40:12

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:17:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-12T19:39:53', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f84a57cd-394d-43ad-9f39-48ea46bcc20d'	System	13 Nov 2020 02:40:12
User entered 'None (0)'	System	13 Nov 2020 02:40:12

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:17:05

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-12T19:39:56', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f84a57cd-394d-43ad-9f39-48ea46bcc20d'	System	13 Nov 2020 02:40:12
User entered 'None (0)'	System	13 Nov 2020 02:40:12

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:17:05

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-12T19:40:02', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f84a57cd-394d-43ad-9f39-48ea46bcc20d'	System	13 Nov 2020 02:40:12
User entered 'No (N)'	System	13 Nov 2020 02:40:12

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:17:05

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-12T19:40:07', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f84a57cd-394d-43ad-9f39-48ea46bcc20d'	System	13 Nov 2020 02:40:12
User entered '12 Nov 2020 19:40'	System	13 Nov 2020 02:40:12

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:17:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Nov 2020 12:00'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:17:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

US3792094

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:17:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	13 Nov 2020 18:51:10

US3792094

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:17:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Nov 2020'	Ann Marie Milliken	13 Nov 2020 18:51:10
	(b) (4)	

US3792094

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:17:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken (b) (4)	13 Nov 2020 18:51:10

US3792094

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:17:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Ann Marie Milliken (b) (4)	13 Nov 2020 18:51:10

US3792094

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:17:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ann Marie Milliken	13 Nov 2020 18:51:16
	(b) (4)	

US3792094

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:17:05

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 18:51:16

US3792094

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:17:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	20 Nov 2020 18:13:11

US3792094

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:17:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Nov 2020'	Ann Marie Milliken	20 Nov 2020 18:13:11
	(b) (4)	

US3792094

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:17:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken (b) (4)	20 Nov 2020 18:13:11

US3792094

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:17:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Ann Marie Milliken (b) (4)	20 Nov 2020 18:13:11

US3792094

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:17:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	20 Nov 2020 18:14:07

US3792094

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:17:05

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 18:14:07

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '20 Nov 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '24 Nov 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '27 Nov 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '01 Dec 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '04 Dec 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '08 Dec 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '11 Dec 2022 00:01'	System	20 Nov 2020 12:14:31

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:17:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '15 Dec 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:17:05

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:29:56
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	23 Oct 2020 22:32:48

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:25:34
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:02
User entered 'USA-US057-2020-mRNA-1273-P301000001'	System	26 Oct 2020 22:00:57
User entered 'New'	(b) (4), (b) (6)	26 Oct 2020 22:00:57

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:25:39
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Acute kidney injury, LLT: Acute kidney injury - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 00:36:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	05 Nov 2020 00:36:35
Data point term sent to Coder	System	05 Nov 2020 00:35:55
Coding entries removed.	Norma Frederick (b) (4)	05 Nov 2020 00:35:02
User entered 'ACUTE KIDNEY INJURY' reason for change: Data Entry Error	(b) (4)	05 Nov 2020 00:35:02
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Renal impairment, LLT: Function kidney decreased - version MedDRA\\23.0.	Norma Frederick (b) (4)	05 Nov 2020 00:35:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 22:40:35
Data point term sent to Coder	(b) (4)	23 Oct 2020 22:40:35
User entered 'DECREASED KIDNEY FUNCTION'	System	23 Oct 2020 22:39:44
	Norma Frederick (b) (4)	23 Oct 2020 22:38:58
	(b) (4)	

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:25:37
User entered 'No (N)'	Norma Frederick (b) (4)	23 Oct 2020 22:38:58

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:25:41
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	23 Oct 2020 22:38:58

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:25:45
User entered 'No (N)'	Norma Frederick (b) (4)	23 Oct 2020 22:38:58

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:25:47
User entered '20 Oct 2020'	Norma Frederick (b) (4)	23 Oct 2020 22:38:58

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:25:54
User entered empty.	Norma Frederick (b) (4)	23 Oct 2020 22:38:58

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 22:38:58

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:25:57
User entered 'No (N)' reason for change: Per Query Resolution	Norma Frederick (b) (4)	05 Nov 2020 00:02:04
User entered 'Yes (Y)'	Norma Frederick (b) (4)	23 Oct 2020 22:38:58

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:25:59
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 19:31:20
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'recovered SAE ' (Site from Safety).	Norma Frederick (b) (4)	05 Nov 2020 00:02:27
User entered '22 Oct 2020' reason for change: Data Entry Error	(b) (4)	05 Nov 2020 00:02:04
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)	02 Nov 2020 15:10:08
User entered empty.	Norma Frederick (b) (4)	23 Oct 2020 22:38:58

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:26:01
User entered empty.	Norma Frederick (b) (4)	23 Oct 2020 22:38:58

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 22:38:58

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:26:03
User closed query 'PV Query: As the event resulted in hospitalization, please confirm the severity of grade 2.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 19:31:49
Query 'PV Query: As the event resulted in hospitalization, please confirm the severity of grade 2.' answered with 'changed severity ' (Site from Safety).	Norma Frederick (b) (4)	05 Nov 2020 00:02:45
User entered 'Grade 4 (Grade 4)' reason for change: Per Query Resolution	(b) (4)	05 Nov 2020 00:02:04
User opened query 'PV Query: As the event resulted in hospitalization, please confirm the severity of grade 2.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 15:12:12
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Norma Frederick (b) (4)	23 Oct 2020 22:38:58

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:26:04
User entered 'Yes (Y)'	Norma Frederick (b) (4)	23 Oct 2020 22:38:58

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:26:10
User entered '0'	Norma Frederick (b) (4)	23 Oct 2020 22:38:58

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:26:12
User entered '0'	Norma Frederick (b) (4)	23 Oct 2020 22:38:58

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:26:14
User entered '1'	Norma Frederick (b) (4)	23 Oct 2020 22:38:58

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:26:30
User entered '20 Oct 2020'	Norma Frederick (b) (4)	23 Oct 2020 22:38:58

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:26:34
User entered '22 Oct 2020'	Norma Frederick (b) (4)	23 Oct 2020 22:38:58

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:26:37
User entered 'No (N)'	Norma Frederick (b) (4)	23 Oct 2020 22:38:58

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:26:42
User entered empty.	Norma Frederick (b) (4)	23 Oct 2020 22:38:58

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:28:00
User entered '0'	Norma Frederick (b) (4)	23 Oct 2020 22:38:58

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:28:10
User entered '0'	Norma Frederick (b) (4)	23 Oct 2020 22:38:58

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:28:04
User entered '0'	Norma Frederick (b) (4)	23 Oct 2020 22:38:58

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:28:06
User entered 'Not Related (NOT RELATED)'	Norma Frederick (b) (4)	23 Oct 2020 22:38:58

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:28:08
User entered 'Not Related (NOT RELATED)'	Norma Frederick (b) (4) (b) (4)	23 Oct 2020 22:38:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCGs p. 35, Action taken with investigational product should be marked as "Not Applicable" only If adverse event started BEFORE first dose, If adverse event started and ended during a time period when study dose was interrupted (not given/held) or If adverse event started AFTER last dose. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 14:11:06
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:28:47
User closed query 'PV Query: PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will be receiving further IP doses, please update action taken to None.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 19:32:18
Query 'PV Query: PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will be receiving further IP doses, please update action taken to None.' answered with 'updated please remove query' (Site from Safety).	Norma Frederick (b) (4) (b) (4)	05 Nov 2020 00:04:51
Query 'Per CDM: Per CCGs p. 35, Action taken with investigational product should be marked as "Not Applicable" only If adverse event started BEFORE first dose, If adverse event started and ended during a time period when study dose was interrupted (not given/held) or If adverse event started AFTER last dose. Please review and update as appropriate. ' answered with 'changed to NONE' (Site from DM).	Norma Frederick (b) (4) (b) (4)	05 Nov 2020 00:02:58
User entered 'None (NONE)' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	05 Nov 2020 00:02:04
User opened query 'PV Query: PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will be receiving further IP doses, please update action taken to None.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 15:11:19

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Per CCGs p. 35, Action taken with investigational product should be marked as "Not Applicable" only If adverse event started BEFORE first dose, If adverse event started and ended during a time period when study dose was interrupted (not given/held) or If adverse event started AFTER last dose. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 08:02:59
User entered 'Not Applicable (NOT APPLICABLE)'	Norma Frederick (b) (4)	23 Oct 2020 22:38:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:28:19
User entered '0'	Norma Frederick (b) (4)	23 Oct 2020 22:38:58

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:28:24
User entered '1'	Norma Frederick (b) (4)	23 Oct 2020 22:38:58

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:28:37
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 22:28:34
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:28:25
User entered '0'	Norma Frederick (b) (4)	23 Oct 2020 22:38:58
	(b) (4)	

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:28:35
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 19:32:26
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated to recovered' (Site from Safety).	Norma Frederick (b) (4) (b) (4)	05 Nov 2020 00:03:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	05 Nov 2020 00:02:04
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 15:10:18
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Norma Frederick (b) (4) (b) (4)	23 Oct 2020 22:38:58

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:28:39
User entered empty.	Norma Frederick (b) (4)	23 Oct 2020 22:38:58

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV query: Please provide subject's medical history including preexisting conditions that may impact renal function.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 11:49:50
User closed query 'PV Query: Please provide any additional treatment given for the event. Please add all treatment medications to CM eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 11:49:48
Query 'PV Query: Please provide any additional treatment given for the event. Please add all treatment medications to CM eCRF (including dates of administration, dose, units, frequency, route and indication).' answered with 'updated CM eCRF' (Site from Safety).	Norma Frederick (b) (4)	06 Nov 2020 20:47:10
Query 'PV query: Please provide subject's medical history including preexisting conditions that may impact renal function.' answered with 'updated medical history eCRF' (Site from Safety).	Norma Frederick (b) (4)	06 Nov 2020 20:47:01
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)	05 Nov 2020 19:33:07
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)	05 Nov 2020 19:33:01
User closed query 'PV Query: Please provide any relevant laboratory (i.e. electrolytes, BUN, creatinine, GFR on admission and discharge) and diagnostic test results (i.e. renal ultrasound, CT). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 19:32:53
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 19:32:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

[Narrative](#)

Audit	User	Time (GMT)
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 'send med records to safety ' (Site from Safety).	Norma Frederick (b) (4)	05 Nov 2020 01:40:10
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'no covid 19 test done ' (Site from Safety).	Norma Frederick (b) (4)	05 Nov 2020 01:39:48
Query 'PV Query: Please provide any relevant laboratory (i.e. electrolytes, BUN, creatinine, GFR on admission and discharge) and diagnostic test results (i.e. renal ultrasound, CT). Please include units and reference ranges if applicable.' answered with 'included in uploaded medical records ' (Site from Safety).	Norma Frederick (b) (4)	05 Nov 2020 01:39:37
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'added to con meds list' (Site from Safety).	Norma Frederick (b) (4)	05 Nov 2020 00:03:35
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)	02 Nov 2020 15:12:31
User opened query 'PV query: Please provide subject's medical history including preexisting conditions that may impact renal function.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 15:12:24
User opened query 'PV Query: Please provide any additional treatment given for the event. Please add all treatment medications to CM eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 15:11:40

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

[Narrative](#)

Audit	User	Time (GMT)
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)	02 Nov 2020 15:10:53
User opened query 'PV Query: Please provide any relevant laboratory (i.e. electrolytes, BUN, creatinine, GFR on admission and discharge) and diagnostic test results (i.e. renal ultrasound, CT). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 15:10:43
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 15:10:37
User entered 'Sub I note: spoke with patient for day 15 safety follow up phone call. Woke up Tuesday morning 10.20.20 and his entire body was swollen. Went to the hospital and was admitted. Released yesterday , (10/22/2020). His kidney function was down to 44%. Was given lasix, which helped.'	Norma Frederick (b) (4)	23 Oct 2020 22:38:58

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 22:38:58

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Oct 2020 22:38:58

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:17:05

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Oct 2020 22:38:58

US3792094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Lower respiratory tract disorders (excl obstruction and infection), HLT: Pulmonary oedemas, PT: Pulmonary congestion, LLT: Pulmonary congestion - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:20:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:20:24
Data point term sent to Coder	System	06 Nov 2020 21:03:49
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 21:02:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 21:02:54
User entered 'pulmonary congestion' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 21:02:54
Data point term sent to Coder	System	06 Nov 2020 21:02:47
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 21:02:28
DataPoint Un-verified.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 21:02:28
User entered empty; reason for change Data Entry Error	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 21:02:28
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:29:50
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Lower respiratory tract disorders (excl obstruction and infection), HLT: Pulmonary oedemas, PT: Pulmonary congestion, LLT: Pulmonary congestion - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 00:17:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 00:17:31
Data point term sent to Coder	System	05 Nov 2020 00:16:37
User entered 'pulmonary congestion'	Norma Frederick (b) (4) (b) (4)	05 Nov 2020 00:15:58

US3792094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 21:02:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 21:02:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Norma Frederick (b) (4)	06 Nov 2020 21:02:54
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 21:02:28
DataPoint Un-verified.	Norma Frederick (b) (4)	06 Nov 2020 21:02:28
User entered empty; reason for change Data Entry Error	Norma Frederick (b) (4)	06 Nov 2020 21:02:28
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:36
User entered 'Yes (Y)'	Norma Frederick (b) (4)	05 Nov 2020 00:15:58

US3792094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:40
User entered 'No (N)'	Norma Frederick (b) (4)	05 Nov 2020 00:15:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:58
User entered 'No (N)'	Norma Frederick (b) (4)	05 Nov 2020 00:15:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:31:03
User entered '20 Oct 2020'	Norma Frederick (b) (4)	05 Nov 2020 00:15:58

US3792094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:31:05
User entered empty.	Norma Frederick (b) (4)	05 Nov 2020 00:15:58
	(b) (4)	

US3792094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 00:15:58

US3792094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:31:07
User entered 'No (N)'	Norma Frederick (b) (4)	05 Nov 2020 00:15:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:31:21
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	05 Nov 2020 00:16:34
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	05 Nov 2020 00:16:34
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	05 Nov 2020 00:15:58
User entered '22 Oct 2020'	Norma Frederick (b) (4) (b) (4)	05 Nov 2020 00:15:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:31:30
User entered empty.	Norma Frederick (b) (4)	05 Nov 2020 00:15:58
	(b) (4)	

US3792094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 00:15:58

US3792094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:31:33
User entered 'Grade 1/Mild (Grade 1/Mild)'	Norma Frederick (b) (4)	05 Nov 2020 00:15:58

US3792094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 22:32:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:31:43
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	05 Nov 2020 00:15:58

US3792094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	05 Nov 2020 00:15:58

US3792094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	05 Nov 2020 00:15:58

US3792094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	05 Nov 2020 00:15:58

US3792094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	05 Nov 2020 00:15:58

US3792094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	05 Nov 2020 00:15:58

US3792094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	05 Nov 2020 00:15:58

US3792094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4)	05 Nov 2020 00:15:58
	(b) (4)	

US3792094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	05 Nov 2020 00:15:58

US3792094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	05 Nov 2020 00:15:58

US3792094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	05 Nov 2020 00:15:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Norma Frederick (b) (4)	05 Nov 2020 00:15:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Norma Frederick (b) (4)	05 Nov 2020 00:15:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Norma Frederick (b) (4)	05 Nov 2020 00:15:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

[None](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4)	05 Nov 2020 00:15:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Norma Frederick (b) (4) (b) (4)	05 Nov 2020 00:15:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	05 Nov 2020 00:15:58

US3792094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Norma Frederick (b) (4)	05 Nov 2020 00:16:34
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Norma Frederick (b) (4)	05 Nov 2020 00:15:58

US3792094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	05 Nov 2020 00:15:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	05 Nov 2020 00:15:58

US3792094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 00:15:58

US3792094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:17:05

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 00:15:58

US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLGT: Metabolic, nutritional and blood gas investigations, HLT: Carbohydrate tolerance analyses (incl diabetes), PT: Blood glucose increased, LLT: Blood glucose increased - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 19:07:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 19:07:49
Data point term sent to Coder	System	13 Nov 2020 19:06:28
User entered 'ELEVATED BLOOD GLUCOSE'	Scarlett Hammett (b) (4)	13 Nov 2020 19:06:23

US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:06:23

US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:06:23

US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:06:23

US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:06:23

US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:06:23

US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 19:06:23

US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:06:23

US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:06:23

US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:06:23

US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 19:06:23

US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:06:23

US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:06:23

US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:06:23

US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:06:23

US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:06:23

US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:06:23

US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:06:23

US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:06:23

US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:06:23

US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:06:23

US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:06:23

US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:06:23

US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:06:23

US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:06:23

US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Scarlett Hammett (b) (4)	13 Nov 2020 19:06:23

US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

[None](#)

Audit	User	Time (GMT)
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:06:23

US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:06:23

US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:06:23

US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Scarlett Hammett (b) (4)	13 Nov 2020 19:06:23

US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:06:23

US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:06:23

US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	13 Nov 2020 19:06:23

US3792094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:17:05

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 19:06:23

US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal neoplasms, PT: Renal cyst, LLT: Cyst of kidney - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 19:09:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 19:09:48
Data point term sent to Coder	System	13 Nov 2020 19:08:32
User entered 'RIGHT KIDNEY CYST'	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:03

US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:08:03

US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:08:03

US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:08:03

US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:08:03

US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:08:03

US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 19:08:03

US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:08:03

US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:08:03

US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:08:03

US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 19:08:03

US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:08:03

US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:08:03

US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:08:03

US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:08:03

US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:08:03

US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:08:03

US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:08:03

US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:08:03

US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:08:03

US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:08:03

US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:08:03

US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:08:03

US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:08:03

US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:03

US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:03

US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

[None](#)

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	13 Nov 2020 19:08:26
User entered '1' reason for change: Data Entry Error	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:26
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
	System	13 Nov 2020 19:08:03
User entered '0'	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:03
	(b) (4)	

US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:08:03

US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:08:03

US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:03

US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:08:03

US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:08:03

US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	13 Nov 2020 19:08:03

US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:17:05

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 19:08:03

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:17:05

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	04 Nov 2020 23:53:21

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:17:05

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: PREGABALIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 20:59:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 20:59:27
Data point term sent to Coder	System	06 Nov 2020 20:58:41
User entered 'pregabalin'	Norma Frederick (b) (4)	06 Nov 2020 20:58:25

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:17:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:58:25

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:17:05

[Indication](#)

Audit	User	Time (GMT)
User entered 'diabetic neuropathy'	Norma Frederick (b) (4)	06 Nov 2020 20:58:25

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:17:05

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:58:25

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:17:05

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Norma Frederick (b) (4)	06 Nov 2020 20:58:25

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:17:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:58:25

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:17:05

[Frequency](#)

Audit	User	Time (GMT)
User entered 'three times daily (TID)'	Norma Frederick (b) (4)	06 Nov 2020 20:58:25

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:17:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:58:25

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:17:05

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	06 Nov 2020 20:58:25

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:17:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 20:58:25
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:17:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Norma Frederick (b) (4)	06 Nov 2020 20:58:25
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:58:25

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:17:05

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:58:25

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:17:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 20:58:25
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:17:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:58:25

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:17:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	06 Nov 2020 20:58:25

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 20:58:25

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 20:58:25

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:17:05

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS, PRODUCT: EMPAGLIFLOZIN, PRODUCTSYNONYM: JARDIANCE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 21:00:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 21:00:33
Data point term sent to Coder	System	06 Nov 2020 20:59:43
User entered 'jardiance'	Norma Frederick (b) (4)	06 Nov 2020 20:59:04

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:17:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 20:59:04

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:17:05

[Indication](#)

Audit	User	Time (GMT)
User entered 'diabetes mellitus, type 2'	Norma Frederick (b) (4)	06 Nov 2020 20:59:04

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:17:05

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '25'	Norma Frederick (b) (4)	06 Nov 2020 20:59:04
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:17:05

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Norma Frederick (b) (4)	06 Nov 2020 20:59:04
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:17:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:59:04

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:17:05

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Norma Frederick (b) (4)	06 Nov 2020 20:59:04

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:17:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:59:04

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:17:05

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	06 Nov 2020 20:59:04
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:17:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:59:04

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:17:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Norma Frederick (b) (4)	06 Nov 2020 20:59:04
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:59:04

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:17:05

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:59:04
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:17:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:59:04

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:17:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 22:04:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 22:04:32
User entered 'No (N)' reason for change: Data Entry Error	Norma Frederick (b) (4)	06 Nov 2020 22:04:32
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 20:59:04
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 20:59:04

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:17:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 20:59:04

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 20:59:04

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 20:59:04

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:17:05

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:32:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:32:24
Data point term sent to Coder	System	06 Nov 2020 21:00:45
User entered 'carvedilol'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:59:57

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:17:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:59:57

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:17:05

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypertension'	Norma Frederick (b) (4)	06 Nov 2020 20:59:57

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:17:05

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '25'	Norma Frederick (b) (4)	06 Nov 2020 20:59:57
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:17:05

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Norma Frederick (b) (4)	06 Nov 2020 20:59:57
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:17:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:59:57

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:17:05

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Norma Frederick (b) (4)	06 Nov 2020 20:59:57

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:17:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:59:57

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:17:05

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	06 Nov 2020 20:59:57

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:17:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:59:57

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:17:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:59:57

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:59:57

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:17:05

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:59:57

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:17:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 20:59:57
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:17:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:59:57

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:17:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Nov 2020 20:59:57

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 20:59:57

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 20:59:57

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:17:05

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 22:09:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 22:09:27
Data point term sent to Coder	System	06 Nov 2020 22:08:20
User entered 'Tamsulosin'	Norma Frederick (b) (4)	06 Nov 2020 22:07:31

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:17:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:07:31

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:17:05

[Indication](#)

Audit	User	Time (GMT)
User entered 'benign prostatic hyperplasia'	Norma Frederick (b) (4)	06 Nov 2020 22:07:31

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:17:05

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '0.4'	Norma Frederick (b) (4)	06 Nov 2020 22:07:31
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:17:05

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Norma Frederick (b) (4)	06 Nov 2020 22:07:31
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:17:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:07:31

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:17:05

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Norma Frederick (b) (4)	06 Nov 2020 22:07:31

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:17:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:07:31

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:17:05

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	06 Nov 2020 22:07:31

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:17:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:07:31
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:17:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Norma Frederick (b) (4)	06 Nov 2020 22:07:31
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:07:31

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:17:05

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 22:07:31

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:17:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:07:31

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:17:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:07:31

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:17:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 22:07:31

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 22:07:31

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 22:07:31

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:17:05

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: DULOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 23:50:22
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 Nov 2020 23:50:22
Data point term sent to Coder	System	06 Nov 2020 22:08:18
User entered 'duloxetine'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:08:11

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:17:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:08:11

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:17:05

[Indication](#)

Audit	User	Time (GMT)
User entered 'diabetic neuropathy'	Norma Frederick (b) (4)	06 Nov 2020 22:08:11

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:17:05

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '60'	Norma Frederick (b) (4)	06 Nov 2020 22:08:11
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:17:05

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Norma Frederick (b) (4)	06 Nov 2020 22:08:11

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:17:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:08:11

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:17:05

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Norma Frederick (b) (4)	06 Nov 2020 22:08:11

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:17:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:08:11

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:17:05

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	06 Nov 2020 22:08:11

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:17:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:08:11

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:17:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	13 Nov 2020 18:39:44
User entered 'UN UNK 2018' reason for change: Data Entry Error	Scarlett Hammett (b) (4)	13 Nov 2020 18:39:44
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	06 Nov 2020 22:08:11
User entered 'un UNK 2918'	Norma Frederick (b) (4)	06 Nov 2020 22:08:11

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:08:11

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:17:05

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 22:08:11
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:17:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:08:11
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:17:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:08:11

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:17:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 22:08:11

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 22:08:11

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 22:08:11

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:17:05

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 23:31:22
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 Nov 2020 23:31:22
Data point term sent to Coder	System	06 Nov 2020 22:09:21
User entered 'aspirin'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:08:43

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:17:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 22:08:43
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:17:05

[Indication](#)

Audit	User	Time (GMT)
User entered 'cardiac prophylaxis'	Norma Frederick (b) (4)	06 Nov 2020 22:08:43

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:17:05

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '81'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:08:43

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:17:05

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Norma Frederick (b) (4)	06 Nov 2020 22:08:43
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:17:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:08:43

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:17:05

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Norma Frederick (b) (4)	06 Nov 2020 22:08:43

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:17:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:08:43

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:17:05

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	06 Nov 2020 22:08:43

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:17:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:08:43
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:17:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	13 Nov 2020 18:40:22
User entered 'UN UNK 2018' reason for change: Data Entry Error	Scarlett Hammett (b) (4)	13 Nov 2020 18:40:22
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	06 Nov 2020 22:08:43
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:08:43

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:08:43

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:17:05

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:08:43

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:17:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:08:43
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:17:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:08:43

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:17:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 22:08:43

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 22:08:43

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 22:08:43

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:17:05

[Name of Medication](#)

Audit	User	Time (GMT)
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 POTASSIUM, PRODUCTSYNONYM: LOSARTIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 22:11:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 22:11:23
Data point term sent to Coder	System	06 Nov 2020 22:10:22
User entered 'losartin'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:09:33

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:17:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 22:09:33
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:17:05

[Indication](#)

Audit	User	Time (GMT)
User entered 'renal prophylaxis'	Norma Frederick (b) (4)	06 Nov 2020 22:09:33

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:17:05

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:09:33

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:17:05

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Norma Frederick (b) (4)	06 Nov 2020 22:09:33
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:17:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:09:33

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:17:05

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Norma Frederick (b) (4)	06 Nov 2020 22:09:33

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:17:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:09:33

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:17:05

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	06 Nov 2020 22:09:33
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:17:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:09:33

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:17:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:09:33

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:09:33

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:17:05

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:09:33

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:17:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:09:33

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:17:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:09:33

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:17:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 22:09:33

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 22:09:33

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 22:09:33

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:17:05

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 22:11:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 22:11:21
Data point term sent to Coder	System	06 Nov 2020 22:10:23
User entered 'pantoprazole'	Norma Frederick (b) (4)	06 Nov 2020 22:10:08

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:17:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:10:08

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:17:05

[Indication](#)

Audit	User	Time (GMT)
User entered 'acid reflux'	Norma Frederick (b) (4)	06 Nov 2020 22:10:08

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:17:05

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '40'	Norma Frederick (b) (4)	06 Nov 2020 22:10:08
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:17:05

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Norma Frederick (b) (4)	06 Nov 2020 22:10:08
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:17:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:10:08

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:17:05

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Norma Frederick (b) (4)	06 Nov 2020 22:10:08

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:17:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:10:08

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:17:05

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	06 Nov 2020 22:10:08

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:17:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:10:08

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:17:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2008'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:10:08

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:10:08

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:17:05

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 22:10:08

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:17:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:10:08

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:17:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:10:08

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:17:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 22:10:08

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 22:10:08

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 22:10:08

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:17:05

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EICOSAPENTAENOIC ACID ETHYL ESTER, PRODUCTSYNONYM: VASCEPA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 22:12:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 22:12:23
Data point term sent to Coder	System	06 Nov 2020 22:11:27
User entered 'vascepa'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:11:24

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:17:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:11:24

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:17:05

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypercholesterolemia'	Norma Frederick (b) (4)	06 Nov 2020 22:11:24

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:17:05

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '2'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:11:24

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:17:05

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'g (g)'	Norma Frederick (b) (4)	06 Nov 2020 22:11:24
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:17:05

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:11:24

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:17:05

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Norma Frederick (b) (4)	06 Nov 2020 22:11:24

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:17:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:11:24

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:17:05

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	06 Nov 2020 22:11:24

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:17:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:11:24

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:17:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Norma Frederick (b) (4)	06 Nov 2020 22:11:24
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:11:24

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:17:05

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:11:24

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:17:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:11:24

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:17:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:11:24

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:17:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Nov 2020 22:11:24

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 22:11:24

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 22:11:24

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:17:05

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 22:13:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 22:13:25
Data point term sent to Coder	System	06 Nov 2020 22:12:29
User entered 'melatonin'	Norma Frederick (b) (4)	06 Nov 2020 22:11:58

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:17:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:11:58

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:17:05

[Indication](#)

Audit	User	Time (GMT)
User entered 'insomnia'	Norma Frederick (b) (4)	06 Nov 2020 22:11:58

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:17:05

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	Norma Frederick (b) (4)	06 Nov 2020 22:11:58
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:17:05

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Norma Frederick (b) (4)	06 Nov 2020 22:11:58
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:17:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:11:58

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:17:05

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Norma Frederick (b) (4)	06 Nov 2020 22:11:58

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:17:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:11:58

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:17:05

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	06 Nov 2020 22:11:58

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:17:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:11:58
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:17:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Norma Frederick (b) (4)	06 Nov 2020 22:11:58
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:11:58

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:17:05

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:11:58

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:17:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:11:58
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:17:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:11:58

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:17:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 22:11:58

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 22:11:58

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 22:11:58

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:17:05

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 22:17:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 22:17:23
Data point term sent to Coder	System	06 Nov 2020 22:16:34
User entered 'albuterol inhaler'	Norma Frederick (b) (4)	06 Nov 2020 22:16:05

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:17:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:16:05

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:17:05

[Indication](#)

Audit	User	Time (GMT)
User entered 'COPD'	Norma Frederick (b) (4)	06 Nov 2020 22:16:05
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:17:05

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:16:05

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:17:05

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'puff (PUFF)'	Norma Frederick (b) (4)	06 Nov 2020 22:16:05

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:17:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:16:05

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:17:05

[Frequency](#)

Audit	User	Time (GMT)
User entered 'three times daily (TID)'	Norma Frederick (b) (4)	06 Nov 2020 22:16:05

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:17:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:16:05

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:17:05

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:16:05

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:17:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:16:05

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:17:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:16:05

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:16:05

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:17:05

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 22:16:05

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:17:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:16:05

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:17:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:16:05

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:17:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	06 Nov 2020 22:16:05

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 22:16:05

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 22:16:05

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:17:05

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE FUROATE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: BREO ELLIPTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:56:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:56:27
Data point term sent to Coder	System	06 Nov 2020 22:17:34
User entered 'BREO ELLIPTA (FLUTCASONE FUROATE VILANTEROL'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:17:33

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:17:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:17:33
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:17:05

[Indication](#)

Audit	User	Time (GMT)
User entered 'COPD'	Norma Frederick (b) (4)	06 Nov 2020 22:17:33
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:17:05

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:17:33

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:17:05

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'puff (PUFF)'	Norma Frederick (b) (4)	06 Nov 2020 22:17:33

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:17:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:17:33

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:17:05

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Norma Frederick (b) (4)	06 Nov 2020 22:17:33

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:17:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:17:33

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:17:05

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:17:33

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:17:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:17:33
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:17:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2018'	Norma Frederick (b) (4)	06 Nov 2020 22:17:33
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:17:33

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:17:05

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:17:33

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:17:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:17:33

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:17:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:17:33

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:17:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 22:17:33

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 22:17:33

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 22:17:33

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:17:05

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:26:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:26:29
Data point term sent to Coder	System	06 Nov 2020 22:19:37
User entered 'LASIX'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:18:43

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:17:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:18:43

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:17:05

[Indication](#)

Audit	User	Time (GMT)
User entered 'ACUTE KIDNEY INJURY'	Norma Frederick (b) (4)	06 Nov 2020 22:18:43

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:17:05

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '40'	Norma Frederick (b) (4)	06 Nov 2020 22:18:43
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:17:05

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Norma Frederick (b) (4)	06 Nov 2020 22:18:43
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:17:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:18:43

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:17:05

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Norma Frederick (b) (4)	06 Nov 2020 22:18:43

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:17:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:18:43

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:17:05

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Norma Frederick (b) (4)	06 Nov 2020 22:18:43

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:17:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:18:43

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:17:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Norma Frederick (b) (4)	06 Nov 2020 22:18:43
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:18:43

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:17:05

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:18:43

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:17:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:18:43

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:17:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:18:43

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:17:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Nov 2020 22:18:43

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 22:18:43

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 22:18:43

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:17:05

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:26:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:26:29
Data point term sent to Coder	System	06 Nov 2020 22:19:37
User entered 'LASIX'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:19:30

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:17:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:19:30

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:17:05

[Indication](#)

Audit	User	Time (GMT)
User entered 'ACUTE KIDNEY INJURY'	Norma Frederick (b) (4)	06 Nov 2020 22:19:30

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:17:05

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '40'	Norma Frederick (b) (4)	06 Nov 2020 22:19:30
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:17:05

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Norma Frederick (b) (4)	06 Nov 2020 22:19:30
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:17:05

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:19:30

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:17:05

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Norma Frederick (b) (4)	06 Nov 2020 22:19:30

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:17:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:19:30

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:17:05

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	06 Nov 2020 22:19:30
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:17:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:19:30

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:17:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:19:30

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:19:30

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:17:05

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:19:30
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:17:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '05 Nov 2020'	Norma Frederick (b) (4)	06 Nov 2020 22:19:30
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:17:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:19:30

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:17:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 22:19:30

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 22:19:30

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 22:19:30

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:17:05

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:28:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:28:27
Data point term sent to Coder	System	06 Nov 2020 22:21:39
User entered 'INSULIN GLARGINE'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:20:50

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:17:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:20:50

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:17:05

[Indication](#)

Audit	User	Time (GMT)
User entered 'DIABETES MELLITUS TYPE 2'	Norma Frederick (b) (4)	06 Nov 2020 22:20:50

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:17:05

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '45'	Norma Frederick (b) (4)	06 Nov 2020 22:20:50
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:17:05

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'IU (IU)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:20:50

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:17:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:20:50
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:17:05

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Norma Frederick (b) (4)	06 Nov 2020 22:20:50

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:17:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:20:50

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:17:05

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Subcutaneous (SUBCUTANEOUS)'	Norma Frederick (b) (4)	06 Nov 2020 22:20:50

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:17:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:20:50

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:17:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:20:50

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:20:50

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:17:05

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:20:50

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:17:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '28 Oct 2020'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:20:50

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:17:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:20:50

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:17:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 22:20:50

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 22:20:50

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 22:20:50

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:17:05

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE;PARACETAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 22:05:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 22:05:52
Data point term sent to Coder Coding entries removed.	System Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:43:37 13 Nov 2020 18:42:51
User entered 'ACETAMINOPHEN 325MG / OXYCODONE 5' reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:42:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 22:38:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 22:38:22
Data point term sent to Coder User entered 'ACETAMINOPHEN'	System Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:22:41 06 Nov 2020 22:21:51

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:17:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:21:51
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:17:05

[Indication](#)

Audit	User	Time (GMT)
User entered 'ACUTE KIDNEY INJURY'	Norma Frederick (b) (4)	06 Nov 2020 22:21:51

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:17:05

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '5/325'	Norma Frederick (b) (4)	06 Nov 2020 22:21:51
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:17:05

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Norma Frederick (b) (4)	06 Nov 2020 22:21:51
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:17:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:21:51
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:17:05

[Frequency](#)

Audit	User	Time (GMT)
User entered 'four times daily (QID)'	Norma Frederick (b) (4)	06 Nov 2020 22:21:51

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:17:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:21:51

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:17:05

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	06 Nov 2020 22:21:51

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:17:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:21:51
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:17:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:21:51

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:21:51

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:17:05

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:21:51

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:17:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:21:51

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:17:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:21:51

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:17:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	06 Nov 2020 22:21:51

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 22:21:51

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 22:21:51

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:17:05

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:52:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:52:28
Data point term sent to Coder	System	06 Nov 2020 22:23:41
User entered 'HUMALOG'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:23:40

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:17:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:23:40

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:17:05

[Indication](#)

Audit	User	Time (GMT)
User entered 'ELEVATED BLOOD GLUCOSE'	Norma Frederick (b) (4)	06 Nov 2020 22:23:40

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:17:05

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:23:40

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:17:05

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'IU (IU)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:23:40

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:17:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:23:40

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:17:05

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Norma Frederick (b) (4)	06 Nov 2020 22:23:40

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:17:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:23:40

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:17:05

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Subcutaneous (SUBCUTANEOUS)'	Norma Frederick (b) (4)	06 Nov 2020 22:23:40

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:17:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:23:40

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:17:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Norma Frederick (b) (4)	06 Nov 2020 22:23:40
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:23:40

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:17:05

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:23:40

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:17:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:23:40

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:17:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:23:40

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:17:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Nov 2020 22:23:40

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 22:23:40

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 22:23:40

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:17:05

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 18:46:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 18:46:48
Data point term sent to Coder	System	13 Nov 2020 18:45:44
User entered 'HUMALOG'	Scarlett Hammett (b) (4)	13 Nov 2020 18:45:25

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:17:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:45:25

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:17:05

[Indication](#)

Audit	User	Time (GMT)
User entered 'ELEVATED BLOOD GLUCOSE'	Scarlett Hammett (b) (4)	13 Nov 2020 18:45:25

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:17:05

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:45:25

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:17:05

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'IU (IU)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:45:25

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:17:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:45:25

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:17:05

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:45:25

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:17:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:45:25

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:17:05

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Subcutaneous (SUBCUTANEOUS)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:45:25

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:17:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:45:25

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:17:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:45:25

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:45:25

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:17:05

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:45:25

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:17:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:45:25

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:17:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:45:25

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:17:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Nov 2020 18:45:25

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 18:45:25

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Nov 2020 18:45:25

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:17:05

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 18:49:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 18:49:47
Data point term sent to Coder	System	13 Nov 2020 18:48:52
User entered 'TRAZODONE'	Scarlett Hammett (b) (4)	13 Nov 2020 18:47:53

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:17:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:47:53

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:17:05

[Indication](#)

Audit	User	Time (GMT)
User entered 'INSOMNIA'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:47:53

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:17:05

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:47:53

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:17:05

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)' reason for change: Data Entry Error	Ann Marie Milliken (b) (4)	18 Nov 2020 19:13:21
User entered 'Other (OTHER)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:47:53

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:17:05

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	18 Nov 2020 19:13:21
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	13 Nov 2020 18:47:53
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	(b) (4) 13 Nov 2020 18:47:53

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:17:05

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:47:53

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:17:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:47:53

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:17:05

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:47:53

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:17:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:47:53

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:17:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:47:53

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:47:53

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:17:05

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:47:53

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:17:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '21 Oct 2020'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:47:53

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:17:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:47:53

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:17:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 18:47:53

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 18:47:53

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Nov 2020 18:47:53

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:17:05

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:20:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:20:41
Data point term sent to Coder	System	13 Nov 2020 18:50:54
User entered 'NITROGLYCERIN'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:50:18

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:17:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:50:18

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:17:05

[Indication](#)

Audit	User	Time (GMT)
User entered 'ACUTE KIDNEY INJURY'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:50:18

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:17:05

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '04'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:50:18

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:17:05

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:50:18

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:17:05

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:50:18

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:17:05

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:50:18

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:17:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:50:18

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:17:05

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:50:18

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:17:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered 'SUBLINGUEL'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:50:18

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:17:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:50:18

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:50:18

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:17:05

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:50:18

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:17:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:50:18

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:17:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:50:18

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:17:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 18:50:18

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 18:50:18

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Nov 2020 18:50:18

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:17:05

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 18:53:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 18:53:48
Data point term sent to Coder	System	13 Nov 2020 18:52:57
User entered 'INSULIN GLARGINE'	Scarlett Hammett (b) (4)	13 Nov 2020 18:52:01

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:17:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:52:01

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:17:05

[Indication](#)

Audit	User	Time (GMT)
User entered 'DIABETES MELLITUS TYPE 2'	Scarlett Hammett (b) (4)	13 Nov 2020 18:52:01

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:17:05

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:52:01

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:17:05

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'IU (IU)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:52:01

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:17:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:52:01

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:17:05

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:52:01

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:17:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:52:01

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:17:05

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Subcutaneous (SUBCUTANEOUS)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:52:01

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:17:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:52:01

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:17:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '29 Oct 2020'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:52:01

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:52:01

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:17:05

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:52:01

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:17:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:52:01

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:17:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:52:01

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:17:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 18:52:01

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 18:52:01

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Nov 2020 18:52:01

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:17:05

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN ASPART, PRODUCTSYNONYM: NOVOLOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:19:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:19:41
Data point term sent to Coder	System	13 Nov 2020 18:57:04
User entered 'NOVALOG'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:56:22

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:17:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:56:22

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:17:05

[Indication](#)

Audit	User	Time (GMT)
User entered 'DIABETES MELLITUS TYPE 2'	Scarlett Hammett (b) (4)	13 Nov 2020 18:56:22

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:17:05

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:56:22

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:17:05

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'IU (IU)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:56:22

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:17:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:56:22

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:17:05

[Frequency](#)

Audit	User	Time (GMT)
User entered 'other (OTHER)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:56:22

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:17:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered '6 TIMES PER DAY'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:56:22

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:17:05

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Subcutaneous (SUBCUTANEOUS)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:56:22

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:17:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:56:22

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:17:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2008'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:56:22

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:17:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:56:22

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:17:05

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:56:22

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:17:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:56:22

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:17:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:56:22

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:17:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 18:56:22

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 18:56:22

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:17:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 18:56:22

US3792094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:17:05

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Norma Frederick (b) (4)	06 Nov 2020 20:47:27
User entered 'No (N)'	Norma Frederick (b) (4)	04 Nov 2020 23:58:06

US3792094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:17:05

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020' reason for change: Data Entry Error	Norma Frederick (b) (4)	06 Nov 2020 20:56:50
User entered '6 Nov 2020'	Norma Frederick (b) (4)	06 Nov 2020 20:55:40

US3792094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:17:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'renal ultrasound'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:55:40

US3792094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:17:05

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Norma Frederick (b) (4)	06 Nov 2020 20:56:50
User entered 'Diagnostic (DIAGNOSTIC)'	Norma Frederick (b) (4)	06 Nov 2020 20:55:40

US3792094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:17:05

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:55:40

US3792094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:17:05

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:56:01

US3792094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:17:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'echocardiogram'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:56:01

US3792094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:17:05

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Norma Frederick (b) (4)	06 Nov 2020 20:56:01
	(b) (4)	

US3792094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:17:05

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:56:01

US3792094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 11:17:05

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:56:20

US3792094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 11:17:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'chest x-ray'	Norma Frederick (b) (4)	06 Nov 2020 20:56:20
	(b) (4)	

US3792094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 11:17:05

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Norma Frederick (b) (4)	06 Nov 2020 20:56:20
	(b) (4)	

US3792094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 11:17:05

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:56:20

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:35:03
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'USA-US057-2020-MRNA-1273-P301000001'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:35:00
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Yes (Y)'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:58
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:57
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Yes (Y)'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:53
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:51
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:50
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:48
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Abram'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Burgher'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 11:50:09
User signature succeeded.	(b) (4), (b) (6)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:34:44
Un-reviewed for Safety.	System	05 Nov 2020 19:33:45
User entered '3900 East Camelback Road'	System	05 Nov 2020 19:33:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
Un-reviewed for Safety.	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
User entered '2525 W. Greenway Road' reason for change: Data Entry Error	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered '3900 East Camelback Road'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:42
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Phoenix'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 22:34:40
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
User entered empty.	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 11:50:09
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:34:38
Un-reviewed for Safety.	System	05 Nov 2020 19:33:45
User entered '85018'	System	05 Nov 2020 19:33:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
Un-reviewed for Safety.	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
User entered '85023' reason for change: Data Entry Error	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered '85018'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
User entered 'US'	System	26 Oct 2020 22:02:16

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	09 Nov 2020 11:50:17
User entered '3'	System	09 Nov 2020 11:50:17
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
	(b) (4)	
User entered '2'	System	05 Nov 2020 19:33:45
User entered '1'	System	26 Oct 2020 22:02:16

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:35:03
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'USA-US057-2020-MRNA-1273-P301000001'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:35:00
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Yes (Y)'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:58
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:57
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Yes (Y)'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:53
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:51
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:50
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:48
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Abram'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Burgher'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 11:50:09
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:34:44
Un-reviewed for Safety.	System	05 Nov 2020 19:33:45
User entered '3900 East Camelback Road'	System	05 Nov 2020 19:33:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
Un-reviewed for Safety.	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
User entered '2525 W. Greenway Road' reason for change: Data Entry Error	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered '3900 East Camelback Road'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:42
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Phoenix'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 22:34:40
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
User entered empty.	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 11:50:09
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:34:38
Un-reviewed for Safety.	System	05 Nov 2020 19:33:45
User entered '85018'	System	05 Nov 2020 19:33:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
Un-reviewed for Safety.	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
User entered '85023' reason for change: Data Entry Error	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered '85018'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
User entered 'US'	System	26 Oct 2020 22:02:16

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	09 Nov 2020 11:50:17
User entered '3'	System	09 Nov 2020 11:50:17
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
	(b) (4)	
User entered '2'	System	05 Nov 2020 19:33:45
User entered '1'	System	26 Oct 2020 22:02:16

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:17:05

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
User entered '26/Oct/2020 22:02'	(b) (4) System	26 Oct 2020 22:02:16

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:17:05

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.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 19:33:29
User entered '1'	(b) (4), (b) (6)	26 Oct 2020 22:02:16

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:35:03
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'USA-US057-2020-MRNA-1273-P301000001'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:35:00
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Yes (Y)'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:58
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:57
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Yes (Y)'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:53
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:51
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:50
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:48
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Abram'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Burgher'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 11:50:09
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:34:44
Un-reviewed for Safety.	System	05 Nov 2020 19:33:45
User entered '3900 East Camelback Road'	System	05 Nov 2020 19:33:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
Un-reviewed for Safety.	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
User entered '2525 W. Greenway Road' reason for change: Data Entry Error	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered '3900 East Camelback Road'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:42
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Phoenix'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 22:34:40
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
User entered empty.	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 11:50:09
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:34:38
Un-reviewed for Safety.	System	05 Nov 2020 19:33:45
User entered '85018'	System	05 Nov 2020 19:33:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
Un-reviewed for Safety.	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
User entered '85023' reason for change: Data Entry Error	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered '85018'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
User entered 'US'	System	26 Oct 2020 22:02:16

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	09 Nov 2020 11:50:17
User entered '3'	System	09 Nov 2020 11:50:17
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
	(b) (4)	
User entered '2'	System	05 Nov 2020 19:33:45
User entered '1'	System	26 Oct 2020 22:02:16

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:17:05

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
User entered '05/Nov/2020 19:33'	(b) (4) System	05 Nov 2020 19:33:45

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:17:05

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)	09 Nov 2020 11:50:09
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
	(b) (4)	
User entered '1'	(b) (4), (b) (6)	05 Nov 2020 19:33:45

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

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[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:35:03
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'USA-US057-2020-MRNA-1273-P301000001'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:35:00
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Yes (Y)'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:58
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:57
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Yes (Y)'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:53
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:51
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:50
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:48
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Abram'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Burgher'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 11:50:09
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:34:44
Un-reviewed for Safety.	System	05 Nov 2020 19:33:45
User entered '3900 East Camelback Road'	System	05 Nov 2020 19:33:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
Un-reviewed for Safety.	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
User entered '2525 W. Greenway Road' reason for change: Data Entry Error	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered '3900 East Camelback Road'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:42
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Phoenix'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 22:34:40
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
User entered empty.	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	

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Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 11:50:09
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:34:38
Un-reviewed for Safety.	System	05 Nov 2020 19:33:45
User entered '85018'	System	05 Nov 2020 19:33:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
Un-reviewed for Safety.	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
User entered '85023' reason for change: Data Entry Error	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered '85018'	System	26 Oct 2020 22:00:57

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Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
User entered 'US'	System	26 Oct 2020 22:02:16

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Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:17:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	09 Nov 2020 11:50:17
User entered '3'	System	09 Nov 2020 11:50:17
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
	(b) (4)	
User entered '2'	System	05 Nov 2020 19:33:45
User entered '1'	System	26 Oct 2020 22:02:16

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:17:05

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '09/Nov/2020 06:50'	System	09 Nov 2020 11:50:17

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:17:05

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	09 Nov 2020 11:50:17