

US3632064 (Prod: Grady Health System)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:14:39

All time stamps listed in this document are displayed in GMT

US3632064

Form: Participant Creation

Data signed: (b) (4) 05 Apr 2021 01:11:51

Generated On: 10 Jun 2021 09:14:39

Participant ID

US3632064

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

US3632064

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Mar 2021 12:21:05

Generated On: 10 Jun 2021 09:14:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3632064

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Mar 2021 12:21:05

Generated On: 10 Jun 2021 09:14:39

Date of Birth (MMM yyyy)	(b) (6) 1945
Age	75
Age Units	YEARS
Age (Derived)	75
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Mar 2021 12:21:05

Generated On: 10 Jun 2021 09:14:39

Date of Informed Consent (*dd MMM yyyy*) 09 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

US3632064

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Mar 2021 12:21:05

Generated On: 10 Jun 2021 09:14:39

Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Mar 2021 12:21:05

Generated On: 10 Jun 2021 09:14:39

Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 22 Apr 2021 15:41:05

Generated On: 10 Jun 2021 09:14:39

Condition	BASAL CELL CARCINOMA (SKIN CANCER)
Start date (dd MMM yyyy)	1 JUL 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	1 JUL 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUL 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 22 Apr 2021 15:41:05

Generated On: 10 Jun 2021 09:14:39

Condition	SKIN CANCER CELLS HAVE BEEN REMOVED- 6 DIFFERENT PROCEDURES IN 30 YEARS PERIOD (2 WERE MELANOMA AND THE REST WERE BCC)
Start date (dd MMM yyyy)	1 UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

US3632064

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 22 Apr 2021 15:41:05

Generated On: 10 Jun 2021 09:14:39

Condition	THYROID GLAND REMOVED (PARTIAL REMOVAL)
Start date (dd MMM yyyy)	1 UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	1 UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 22 Apr 2021 15:41:05

Generated On: 10 Jun 2021 09:14:39

Condition	SKIN CANCER- MONITORED EVERY 6 MONTHS
Start date (dd MMM yyyy)	1 UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	_____
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3632064

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 22 Apr 2021 15:41:05

Generated On: 10 Jun 2021 09:14:39

Condition	PARKINSON'S DISEASE (SLOW PROGRESSION)
Start date (dd MMM yyyy)	1 UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	_____
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3632064

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 22 Apr 2021 15:41:05

Generated On: 10 Jun 2021 09:14:39

Condition	HIGH BLOOD PRESSURE
Start date (dd MMM yyyy)	1 UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 22 Apr 2021 15:41:05

Generated On: 10 Jun 2021 09:14:39

Condition	HIGH CHOLESTEROL
Start date (dd MMM yyyy)	1 UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 22 Apr 2021 15:41:05

Generated On: 10 Jun 2021 09:14:39

Condition	BENIGN PROSTATIC HYPERPLASIA (BPH)
Start date (dd MMM yyyy)	1 UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	_____
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 22 Apr 2021 15:41:05

Generated On: 10 Jun 2021 09:14:39

Condition	ROSACEA
Start date (dd MMM yyyy)	1 UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3632064

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 22 Apr 2021 15:41:05

Generated On: 10 Jun 2021 09:14:39

Condition	SEVERE OBESITY WITH A BMI OVER 40
Start date (dd MMM yyyy)	1 UNK 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	_____
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 22 Apr 2021 15:41:05

Generated On: 10 Jun 2021 09:14:39

Condition	THYROID NODULES (RESULTED IN A PARTIAL THYROID REMOVAL)
Start date (dd MMM yyyy)	1 UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	1 UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

US3632064

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Mar 2021 12:21:05

Generated On: 10 Jun 2021 09:14:39

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	09 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:44 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 13:44
Height (<i>xxx.x</i>)	68 in
Weight (<i>xxx.x</i>)	267.2 lb
BMI (<i>xxx.x</i>)	40.71257 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Mar 2021 12:21:05

Generated On: 10 Jun 2021 09:14:39

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

09 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Mar 2021 12:21:05

Generated On: 10 Jun 2021 09:14:39

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

GOES TO GROCERY STORE

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Mar 2021 12:21:05

Generated On: 10 Jun 2021 09:14:39

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 08 Mar 2021 14:36:42

Generated On: 10 Jun 2021 09:14:39

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 09 SEP 2020

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

Folder OID VISIT1

US3632064

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 08 Mar 2021 14:36:42

Generated On: 10 Jun 2021 09:14:39

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

What was the participant's randomization number? 190035

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

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

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

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

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

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

Liver Disease Yes No

Human Immunodeficiency Virus (HIV) infection Yes No

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 08 Mar 2021 14:36:42

Generated On: 10 Jun 2021 09:14:39

Height	ND - Not Done
Weight	ND - Not Done

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Mar 2021 14:36:42

Generated On: 10 Jun 2021 09:14:39

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	09 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:44 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 13:44
Temperature (<i>xxx.x</i>)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	45 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Mar 2021 14:36:42

Generated On: 10 Jun 2021 09:14:39

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	09 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	15:57 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 15:57
Temperature (<i>xxx.x</i>)	96.8 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	45 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	73 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 08 Mar 2021 14:36:42

Generated On: 10 Jun 2021 09:14:39

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

09 SEP 2020

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

US3632064

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 08 Mar 2021 14:36:42

Generated On: 10 Jun 2021 09:14:39

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) 09 SEP 2020

What was the treatment time? (00:00-23:59) 15:14 (24 HR)

Treatment Date and Time (derived) 09 SEP 2020 15:14

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

US3632064

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Mar 2021 14:36:42

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 08 Mar 2021 14:36:42

Generated On: 10 Jun 2021 09:14:39

Collection date (<i>dd MMM yyyy</i>)			09 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:26	09 SEP 2020 14:26
Nasopharyngeal Swab 2	No		

US3632064

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:36:42

Generated On: 10 Jun 2021 09:14:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

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 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 SEP 2020 16:00

PC Open Date & Time 09 SEP 2020 15:34

PC Close Date & Time 09 SEP 2020 18:04

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 97.3 °F

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

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

PC Time Stamp 09 SEP 2020 22:48
PC Open Date & Time 09 SEP 2020 18:59
PC Close Date & Time 10 SEP 2020 11:59

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:39

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	10 SEP 2020 22:39
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:39

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	11 SEP 2020 22:22
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:39

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	12 SEP 2020 22:18
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:39

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	13 SEP 2020 22:34
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:39

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	14 SEP 2020 21:57
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:39

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	15 SEP 2020 21:56
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

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 SEP 2020 16:02

PC Open Date & Time

09 SEP 2020 15:34

PC Close Date & Time

09 SEP 2020 18:04

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	09 SEP 2020 22:49
PC Open Date & Time	09 SEP 2020 18:59
PC Close Date & Time	10 SEP 2020 11:59

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

DAY 2

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	10 SEP 2020 22:41
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

DAY 3

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	11 SEP 2020 22:23
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

DAY 4

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

12 SEP 2020 22:19

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

DAY 5

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	13 SEP 2020 22:35
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

DAY 6

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

14 SEP 2020 21:58

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

DAY 7

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	15 SEP 2020 21:57
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

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

No
Yes

PC Time stamp	09 SEP 2020 16:04
PC Open Date & Time	09 SEP 2020 15:34
PC Close Date & Time	09 SEP 2020 18:04

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

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

No

Yes

PC Time stamp	09 SEP 2020 22:50
PC Open Date & Time	09 SEP 2020 18:59
PC Close Date & Time	10 SEP 2020 11:59

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:39

	Yes <input type="checkbox"/>
PC Time stamp	10 SEP 2020 22:42
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:39

Yes

PC Time stamp	11 SEP 2020 22:24
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:39

Yes

PC Time stamp	12 SEP 2020 22:21
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:39

Yes

PC Time stamp	13 SEP 2020 22:36
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:39

	Yes <input type="checkbox"/>
PC Time stamp	14 SEP 2020 21:59
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:39

	Yes <input type="checkbox"/>
PC Time stamp	15 SEP 2020 21:58
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3632064

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 14:36:42

Generated On: 10 Jun 2021 09:14:39

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 16 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3632064

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:36:42

Generated On: 10 Jun 2021 09:14:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3632064

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 14:36:42

Generated On: 10 Jun 2021 09:14:39

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 24 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3632064

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:36:42

Generated On: 10 Jun 2021 09:14:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3632064

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 14:36:42

Generated On: 10 Jun 2021 09:14:39

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 30 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3632064

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:36:42

Generated On: 10 Jun 2021 09:14:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3632064

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 08 Mar 2021 14:36:43

Generated On: 10 Jun 2021 09:14:39

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 7 OCT 2020

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

Folder OID VISIT2

US3632064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Mar 2021 14:36:43

Generated On: 10 Jun 2021 09:14:39

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	7 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	12:10 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 12:10
Temperature (<i>xxx.x</i>)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	85 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	59 mmHg
Diastolic Blood Pressure units	MMHG

US3632064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Mar 2021 14:36:43

Generated On: 10 Jun 2021 09:14:39

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	7 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	14:44 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 14:44
Temperature (<i>xxx.x</i>)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	51 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3632064

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Mar 2021 14:36:43

Generated On: 10 Jun 2021 09:14:39

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

7 OCT 2020

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

US3632064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 08 Mar 2021 14:36:43

Generated On: 10 Jun 2021 09:14:39

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) 7 OCT 2020

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

Treatment Date and Time (derived) 7 OCT 2020 14:14

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

US3632064

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Mar 2021 14:36:43

Generated On: 10 Jun 2021 09:14:39

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 7 OCT 2020

Collection time (*00:00-23:59*) 12:50 (24 HR)

Collection date and time (derived) 7 OCT 2020 12:50

US3632064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 08 Mar 2021 14:36:43

Generated On: 10 Jun 2021 09:14:39

Collection date (<i>dd MMM yyyy</i>)			7 OCT 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:52	7 OCT 2020 12:52
Nasopharyngeal Swab 2	No		

US3632064

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:36:43

Generated On: 10 Jun 2021 09:14:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.8 °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 07 OCT 2020 14:48

PC Open Date & Time 07 OCT 2020 14:34

PC Close Date & Time 07 OCT 2020 17:04

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.5 °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 OCT 2020 23:10
PC Open Date & Time 07 OCT 2020 17:59
PC Close Date & Time 08 OCT 2020 11:59

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:39

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	08 OCT 2020 22:35
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:39

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	09 OCT 2020 22:56
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.1 °F

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

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

PC Time Stamp 10 OCT 2020 23:00

PC Open Date & Time 10 OCT 2020 12:00

PC Close Date & Time 11 OCT 2020 11:59

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:39

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	11 OCT 2020 22:38
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:39

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	12 OCT 2020 22:21
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:39

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	13 OCT 2020 22:45
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

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

07 OCT 2020 14:49

PC Open Date & Time

07 OCT 2020 14:34

PC Close Date & Time

07 OCT 2020 17:04

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

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

07 OCT 2020 23:11

PC Open Date & Time

07 OCT 2020 17:59

PC Close Date & Time

08 OCT 2020 11:59

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

DAY 2

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 - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

2

Measure the largest size across any injection site swelling/hardness with the ruler provided.

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp 08 OCT 2020 22:37

PC Open Date & Time 08 OCT 2020 12:00

PC Close Date & Time 09 OCT 2020 11:59

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

DAY 3

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

Please record - **REDNESS AT INJECTION SITE (in mm)**

50

Measure the largest size across any injection site redness with the ruler provided.

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 23:00

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

DAY 4

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	10 OCT 2020 23:01
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

DAY 5

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	11 OCT 2020 22:39
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

DAY 6

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	12 OCT 2020 22:22
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

DAY 7

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

13 OCT 2020 22:45

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

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

No

Yes

PC Time stamp	07 OCT 2020 14:50
PC Open Date & Time	07 OCT 2020 14:34
PC Close Date & Time	07 OCT 2020 17:04

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

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

No
Yes

PC Time stamp	07 OCT 2020 23:12
PC Open Date & Time	07 OCT 2020 17:59
PC Close Date & Time	08 OCT 2020 11:59

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:39

	Yes <input type="checkbox"/>
PC Time stamp	08 OCT 2020 22:38
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:39

	Yes <input type="checkbox"/>
PC Time stamp	09 OCT 2020 23:02
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:39

	Yes <input type="checkbox"/>
PC Time stamp	10 OCT 2020 23:02
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:39

	Yes <input type="checkbox"/>
PC Time stamp	11 OCT 2020 22:40
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:39

	Yes <input type="checkbox"/>
PC Time stamp	12 OCT 2020 22:23
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:39

Yes

PC Time stamp	13 OCT 2020 22:46
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3632064

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 14:36:42

Generated On: 10 Jun 2021 09:14:39

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 14 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3632064

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:36:42

Generated On: 10 Jun 2021 09:14:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3632064

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 14:36:42

Generated On: 10 Jun 2021 09:14:39

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 21 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3632064

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:36:42

Generated On: 10 Jun 2021 09:14:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3632064

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 14:36:42

Generated On: 10 Jun 2021 09:14:39

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 28 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3632064

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:36:42

Generated On: 10 Jun 2021 09:14:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3632064

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 08 Mar 2021 14:36:43

Generated On: 10 Jun 2021 09:14:39

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 04 NOV 2020

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

Folder OID VISIT3

US3632064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Mar 2021 14:36:43

Generated On: 10 Jun 2021 09:14:39

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3632064

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Mar 2021 14:36:43

Generated On: 10 Jun 2021 09:14:39

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.

US3632064

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Mar 2021 14:36:43

Generated On: 10 Jun 2021 09:14:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	04 NOV 2020
Collection time (<i>00:00-23:59</i>)	12:48 (24 HR)
Collection date and time (derived)	04 NOV 2020 12:48

US3632064

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:36:43

Generated On: 10 Jun 2021 09:14:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

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 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

DAY 71

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

No

Yes

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

No

Yes

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

Date and time of submission 17 NOV 2020 11:25:04

Patient Cloud Open Date & Time 16 NOV 2020 00:01

Patient Cloud Close Date & Time 20 NOV 2020 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 NOV 2020 15:28:56
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

DAY 82

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

No

Yes

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

No

Yes

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

Date and time of submission 28 NOV 2020 11:27:57

Patient Cloud Open Date & Time 27 NOV 2020 00:01

Patient Cloud Close Date & Time 01 DEC 2020 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 DEC 2020 09:34:55
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 DEC 2020 08:40:07
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 DEC 2020 15:39:46
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 DEC 2020 01:09:24
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	01 JAN 2021 12:43:10
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	08 JAN 2021 09:52:49
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 JAN 2021 07:40:13
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 JAN 2021 16:44:55
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 JAN 2021 08:07:31
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

DAY 152

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

No

Yes

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

No

Yes

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

Date and time of submission 08 FEB 2021 01:38:11

Patient Cloud Open Date & Time 05 FEB 2021 00:01

Patient Cloud Close Date & Time 09 FEB 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 FEB 2021 07:24:14
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 FEB 2021 13:31:33
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

DAY 173

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

No

Yes

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

No

Yes

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

Date and time of submission 26 FEB 2021 16:47:53

Patient Cloud Open Date & Time 26 FEB 2021 00:01

Patient Cloud Close Date & Time 02 MAR 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 MAR 2021 09:49:47
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

DAY 187

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

No

Yes

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

No

Yes

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

Date and time of submission 12 MAR 2021 09:16:19

Patient Cloud Open Date & Time 12 MAR 2021 00:01

Patient Cloud Close Date & Time 16 MAR 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

DAY 194

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

No

Yes

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

No

Yes

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

Date and time of submission 21 MAR 2021 13:24:33

Patient Cloud Open Date & Time 19 MAR 2021 00:01

Patient Cloud Close Date & Time 23 MAR 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 MAR 2021 22:12:04
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

DAY 208

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

No

Yes

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

No

Yes

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

Date and time of submission 04 APR 2021 18:37:27

Patient Cloud Open Date & Time 02 APR 2021 00:01

Patient Cloud Close Date & Time 06 APR 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 APR 2021 12:14:44
Patient Cloud Open Date & Time	09 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

DAY 222

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

No

Yes

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

No

Yes

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

Date and time of submission 16 APR 2021 13:09:56

Patient Cloud Open Date & Time 16 APR 2021 00:01

Patient Cloud Close Date & Time 20 APR 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 APR 2021 11:09:28
Patient Cloud Open Date & Time	23 APR 2021 00:01
Patient Cloud Close Date & Time	27 APR 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 APR 2021 19:28:14
Patient Cloud Open Date & Time	30 APR 2021 00:01
Patient Cloud Close Date & Time	04 MAY 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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 JUN 2021 00:01
Patient Cloud Close Date & Time	15 JUN 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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 JUN 2021 00:01
Patient Cloud Close Date & Time	29 JUN 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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 JUL 2021 00:01
Patient Cloud Close Date & Time	06 JUL 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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 JUL 2021 00:01
Patient Cloud Close Date & Time	13 JUL 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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 JUL 2021 00:01
Patient Cloud Close Date & Time	20 JUL 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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 JUL 2021 00:01
Patient Cloud Close Date & Time	03 AUG 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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 AUG 2021 00:01
Patient Cloud Close Date & Time	17 AUG 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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 SEP 2021 00:01
Patient Cloud Close Date & Time	07 SEP 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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 SEP 2021 00:01
Patient Cloud Close Date & Time	14 SEP 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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 OCT 2021 00:01
Patient Cloud Close Date & Time	12 OCT 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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 OCT 2021 00:01
Patient Cloud Close Date & Time	19 OCT 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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 OCT 2021 00:01
Patient Cloud Close Date & Time	26 OCT 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission	
Patient Cloud Open Date & Time	29 OCT 2021 00:01
Patient Cloud Close Date & Time	02 NOV 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#) 16 NOV 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission	
Patient Cloud Open Date & Time	26 NOV 2021 00:01
Patient Cloud Close Date & Time	30 NOV 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission	
Patient Cloud Open Date & Time	03 DEC 2021 00:01
Patient Cloud Close Date & Time	07 DEC 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission	
Patient Cloud Open Date & Time	17 DEC 2021 00:01
Patient Cloud Close Date & Time	21 DEC 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission	
Patient Cloud Open Date & Time	24 DEC 2021 00:01
Patient Cloud Close Date & Time	28 DEC 2021 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission	
Patient Cloud Open Date & Time	14 JAN 2022 00:01
Patient Cloud Close Date & Time	18 JAN 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission	
Patient Cloud Open Date & Time	04 FEB 2022 00:01
Patient Cloud Close Date & Time	08 FEB 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission	
Patient Cloud Open Date & Time	11 FEB 2022 00:01
Patient Cloud Close Date & Time	15 FEB 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission	
Patient Cloud Open Date & Time	18 FEB 2022 00:01
Patient Cloud Close Date & Time	22 FEB 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission	
Patient Cloud Open Date & Time	04 MAR 2022 00:01
Patient Cloud Close Date & Time	08 MAR 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission	
Patient Cloud Open Date & Time	08 APR 2022 00:01
Patient Cloud Close Date & Time	12 APR 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission	
Patient Cloud Open Date & Time	15 APR 2022 00:01
Patient Cloud Close Date & Time	19 APR 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission	
Patient Cloud Open Date & Time	22 APR 2022 00:01
Patient Cloud Close Date & Time	26 APR 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission	
Patient Cloud Open Date & Time	06 MAY 2022 00:01
Patient Cloud Close Date & Time	10 MAY 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission	
Patient Cloud Open Date & Time	03 JUN 2022 00:01
Patient Cloud Close Date & Time	07 JUN 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission	
Patient Cloud Open Date & Time	17 JUN 2022 00:01
Patient Cloud Close Date & Time	21 JUN 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#) 28 JUN 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission	
Patient Cloud Open Date & Time	08 JUL 2022 00:01
Patient Cloud Close Date & Time	12 JUL 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2022 00:01
Patient Cloud Close Date & Time	19 JUL 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission	
Patient Cloud Open Date & Time	22 JUL 2022 00:01
Patient Cloud Close Date & Time	26 JUL 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission	
Patient Cloud Open Date & Time	05 AUG 2022 00:01
Patient Cloud Close Date & Time	09 AUG 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission	
Patient Cloud Open Date & Time	19 AUG 2022 00:01
Patient Cloud Close Date & Time	23 AUG 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission	
Patient Cloud Open Date & Time	02 SEP 2022 00:01
Patient Cloud Close Date & Time	06 SEP 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission	
Patient Cloud Open Date & Time	09 SEP 2022 00:01
Patient Cloud Close Date & Time	13 SEP 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission	
Patient Cloud Open Date & Time	16 SEP 2022 00:01
Patient Cloud Close Date & Time	20 SEP 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission	
Patient Cloud Open Date & Time	30 SEP 2022 00:01
Patient Cloud Close Date & Time	04 OCT 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission	
Patient Cloud Open Date & Time	07 OCT 2022 00:01
Patient Cloud Close Date & Time	11 OCT 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission	
Patient Cloud Open Date & Time	21 OCT 2022 00:01
Patient Cloud Close Date & Time	25 OCT 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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°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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Date and time of submission	
Patient Cloud Open Date & Time	11 NOV 2022 00:01
Patient Cloud Close Date & Time	15 NOV 2022 23:59

US3632064

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:14:39

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		05 MAR 2021 09:50:16

US3632064

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 14:36:42

Generated On: 10 Jun 2021 09:14:39

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 2 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3632064

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:36:42

Generated On: 10 Jun 2021 09:14:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3632064

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 01:11:52

Generated On: 10 Jun 2021 09:14:39

Was Contact Attempted? Yes No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 5 JAN 2021

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

Comments PARTICIPANT WAS HOSPITALE
WHEN SC WAS DUE FOR
If Contact Not Made, please provide Comments TIA/CVA, RECORDS HAVE BEEN
SENT

US3632064

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 01:11:52

Generated On: 10 Jun 2021 09:14:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3632064

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 01:11:52

Generated On: 10 Jun 2021 09:14:39

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 4 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3632064

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 01:11:52

Generated On: 10 Jun 2021 09:14:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3632064

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 01:11:52

Generated On: 10 Jun 2021 09:14:39

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 5 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3632064

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 01:11:52

Generated On: 10 Jun 2021 09:14:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3632064

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 05 APR 2021

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

Folder OID VISIT4

US3632064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3632064

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

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.

US3632064

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	05 APR 2021
Collection time (<i>00:00-23:59</i>)	13:34 (24 HR)
Collection date and time (derived)	05 APR 2021 13:34

US3632064

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3632064

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

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 _____

US3632064

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:39

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3632064

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:14:39

Generate Next COVID-19 Assessment

Yes

No

US3632064

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

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 01:11:52

Generated On: 10 Jun 2021 09:14:39

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 8 JAN 2021

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

Folder OID UNBLND_DECIDE

US3632064

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 01:11:52

Generated On: 10 Jun 2021 09:14:39

Date of updated informed consent (<i>dd MMM yyyy</i>)	8 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	8 JAN 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	

US3632064

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 01:11:52

Generated On: 10 Jun 2021 09:14:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	8 JAN 2021
Collection time (<i>00:00-23:59</i>)	12:37 (24 HR)
Collection date and time (derived)	8 JAN 2021 12:37

US3632064

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Apr 2021 01:11:52

Generated On: 10 Jun 2021 09:14:39

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 8 JAN 2021

Collection time (*00:00 - 23:59*) 12:40

Collection Date and Time (derived) 8 JAN 2021 12:40

US3632064

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 12:25:44

Generated On: 10 Jun 2021 09:14:39

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3632064

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Mar 2021 12:25:44

Generated On: 10 Jun 2021 09:14:39

AEID USA-US120-2021-MRNA-1273-P30
1000001

Adverse event TRANSIENT ISCHEMIC ATTACK

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) 31 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 04 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening True

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 31 DEC 2020

Hospital Discharge Date (dd MMM yyyy) 4 JAN 2021

Admitted to ICU? Yes
No
Unknown

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Mar 2021 12:25:44

Generated On: 10 Jun 2021 09:14:39

Number of Days in ICU	1
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	PARTICIPANT CONTINUES TO HAVE RIGHT SIDED WEAKNESS, BUT AMBULATES WITHOUT ASSISTANCE.

Narrative

US3632064

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Mar 2021 12:25:44

Generated On: 10 Jun 2021 09:14:39

ADMITTED TO ICU ON
12/31/2020 DUE TO TIA WITH
SLURRED SPEECH AND RIGHT
HAND WEAKNESS. GIVEN
PLAXIS. ON 01/01/2021 CLEAR
SPEECH AND RIGHT HAND
STRENGTH RESOLVING. MRI
03JAN2021 WITH FINDINGS
COMPATIBLE WITH ACUTE TO
SUBACUTE INFARCT

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

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Apr 2021 01:11:52

Generated On: 10 Jun 2021 09:14:39

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

Yes

No

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

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

Name of Medication MIRABEGRON

Prophylaxis Yes
No

Indication PROSTATE AND BLADDER
ISSUES

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy)	14 JUL 2020
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="radio"/>
	803 <input type="radio"/>
	804 <input checked="" type="radio"/>

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

Name of Medication PRAVASTATIN

Prophylaxis Yes
No

Indication HIGH CHOLESTEROL

Dose per administration 40

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2015

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 4 JAN 2021

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

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

Name of Medication FINASTERIDE

Prophylaxis Yes
No

Indication PROSTATE AND BLADDER ISSUES

Dose per administration 5

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 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

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

Name of Medication AMLODIPINE

Prophylaxis Yes
No

Indication HIGH BLOOD PRESSURE

Dose per administration 5

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

Intramuscular	<input type="radio"/>
Respiratory (Inhalation)	<input type="radio"/>
Intralesional	<input type="radio"/>
Intraperitoneal	<input type="radio"/>
Nasal	<input type="radio"/>
Vaginal	<input type="radio"/>
Rectal	<input type="radio"/>
Intravenous	<input type="radio"/>
Intravenous Bolus	<input type="radio"/>
Intravenous Drip	<input type="radio"/>
Other	<input type="radio"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 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) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

Name of Medication CARBIDOPA LEVODOPA

Prophylaxis Yes
No

Indication PARKINSON'S DISEASE

Dose per administration 25-100

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 2 DEC 2019

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 3

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

Name of Medication IRBESARTAN

Prophylaxis Yes
No

Indication HIGH BLOOD PRESSURE

Dose per administration 300

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2015

Start date completely unknown False

Ongoing? Yes
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

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

Name of Medication METOPROLOL

Prophylaxis Yes
No

Indication HIGH BLOOD PRESSURE

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2015

Start date completely unknown False

Ongoing? Yes
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

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

Name of Medication TAMSULOSIN

Prophylaxis Yes
No

Indication PROSTATE AND BLADDER ISSUES

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 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) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes
No

Indication HIGH BLOOD PRESSURE

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2015

Start date completely unknown False

Ongoing? Yes
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

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

Name of Medication VITAMIN D

Prophylaxis Yes
No

Indication GENERAL HEALTH

Dose per administration 1000

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2015

Start date completely unknown False

Ongoing? Yes
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

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

Name of Medication CALCIUM- VITAMIN D

Prophylaxis Yes
No

Indication GENERAL HEALTH

Dose per administration 600-500

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 27 AUG 2014

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

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

Name of Medication VITAMIN B12

Prophylaxis Yes
No

Indication GENERAL HEALTH

Dose per administration 1000

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 17 JUL 2013

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

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

Name of Medication ASPIRIN

Prophylaxis Yes
No

Indication GENERAL HEALTH

Dose per administration 81

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 31 AUG 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) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

Name of Medication DOXYCYCLINE HYCLATE

Prophylaxis Yes
No

Indication ROSACEA

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

361 of 2121

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2000

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

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

Name of Medication PLAVIX

Prophylaxis Yes
No

Indication TRANSIENT ISCHEMIC ATTACK

Dose per administration 300

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

363 of 2121

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 31 DEC 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 31 DEC 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

Name of Medication PLAVIX

Prophylaxis Yes
No

Indication TIA

Dose per administration 75

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

365 of 2121

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 3 JAN 2021

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

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

Name of Medication LIPITOR

Prophylaxis Yes
No

Indication HIGH CHOLESTEROL

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

367 of 2121

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 12 Apr 2021 01:34:21

Generated On: 10 Jun 2021 09:14:39

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 3 JAN 2021

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

US3632064

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Apr 2021 01:11:52

Generated On: 10 Jun 2021 09:14:39

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3632064

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 05 Apr 2021 01:11:52

Generated On: 10 Jun 2021 09:14:39

Procedure/Surgery date (<i>dd MMM</i> <i>yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
03 JAN 2021	MRI	Adverse Event	

US3632064

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:14:39

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

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 05 Apr 2021 01:11:52

Generated On: 10 Jun 2021 09:14:39

SAEID	USA-US120-2021-MRNA-1273-P30 1000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 05 Apr 2021 01:11:52

Generated On: 10 Jun 2021 09:14:39

SAEID	USA-US120-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	04/JAN/2021 19:37
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.	<input checked="" type="checkbox"/> True

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 05 Apr 2021 01:11:52

Generated On: 10 Jun 2021 09:14:39

SAEID	USA-US120-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	13/JAN/2021 17:26
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	<input checked="" type="checkbox"/> True

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 05 Apr 2021 01:11:52

Generated On: 10 Jun 2021 09:14:39

SAEID	USA-US120-2021-MRNA-1273-P30 1000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	_____
Site Address: City	_____
Site Address: State	GA
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	05/FEB/2021 17:49
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 05 Apr 2021 01:11:52

Generated On: 10 Jun 2021 09:14:39

SAEID	USA-US120-2021-MRNA-1273-P30 1000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	16/FEB/2021 13:11
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

US3632064 (Prod: Grady Health System)

US3632064

Form: Participant Creation

Generated On: 10 Jun 2021 09:14:39

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:24:19
User entered 'US3632064'	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 16:44:36

US3632064

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:14:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:23:03
User entered 'Yes (Y)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 19:16:34

US3632064

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:23:03
User entered '09 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 16:44:37

US3632064

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:23:03
User entered 'Clinic (Clinic)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 19:16:34

US3632064

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:14:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered 'SCRN'	System	09 Sep 2020 19:16:34

US3632064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:24:41
User closed query 'Per GCL Lab Recon: GCL has DOB as 1970, however EDC has DOB reported as 1945. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 09:16:33
Query 'Per GCL Lab Recon: GCL has DOB as 1970, however EDC has DOB reported as 1945. Please review and reconcile.' answered with 'DOB is 1945' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 16:14:58
User opened query 'Per GCL Lab Recon: GCL has DOB as 1970, however EDC has DOB reported as 1945. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 20:58:18
User entered (b) (6) 1945'	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 16:44:38

US3632064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:39

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:24:41
User entered '75'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 19:16:57

US3632064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:39

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered 'YEARS'	System	09 Sep 2020 19:16:57

US3632064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:39

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered '75'	System	09 Sep 2020 19:17:27

US3632064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:39

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:24:41
User entered 'Male (M)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 19:16:57

US3632064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:39

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:24:41
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 19:16:57

US3632064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:39

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:24:41
User entered '1'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 19:16:57

US3632064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:39

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:24:41
User entered '0'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 19:16:57

US3632064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:39

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:24:41
User entered '0'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 19:16:57

US3632064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:39

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:24:41
User entered '0'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 19:16:57

US3632064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:39

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:24:41
User entered '0'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 19:16:57

US3632064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:39

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:24:41
User entered '0'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 19:16:57

US3632064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:39

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:24:41
User entered empty.	Bezuayehu Mandefro (b) (4)	09 Sep 2020 19:16:57

US3632064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:39

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:24:41
User entered '0'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 19:16:57

US3632064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:39

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:24:41
User entered '0'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 19:16:57

US3632064

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:14:39

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:24:53
User entered '09 Sep 2020'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 19:17:27

US3632064

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered 'Sep 2020'	System	09 Sep 2020 19:17:27

US3632064

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered '2020'	System	09 Sep 2020 19:17:27

US3632064

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:14:39

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:24:53
User entered 'Amendment 3 (3)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 19:17:27

US3632064

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:24:53
User entered 'Yes (Y)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 19:17:27

US3632064

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:14:39

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:24:53
User entered empty.	Bezuayehu Mandefro (b) (4)	09 Sep 2020 19:17:27

US3632064

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:14:39

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:24:53
User entered empty.	Bezuayehu Mandefro (b) (4)	09 Sep 2020 19:17:27

US3632064

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:14:39

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:24:53
User entered 'No (N)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 19:17:27

US3632064

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:14:39

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:24:53
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 16:44:37

US3632064

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:14:39

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered '1'	System	09 Sep 2020 19:17:31

US3632064

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:26:33
User entered 'Yes (Y)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 19:17:31

US3632064

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:14:39

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:26:41
User entered 'Yes (Y)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 20:47:57

US3632064

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:14:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User closed query 'Per DM CLR: Only one medical condition/diagnosis should be entered per line. Please review and provide separate entries for each condition. Update eCRF as appropriate. '(Site from DM).	(b) (4), (b) (6)	28 Oct 2020 10:11:17
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLG: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 21:32:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 21:32:42
Query 'Per DM CLR: Only one medical condition/diagnosis should be entered per line. Please review and provide separate entries for each condition. Update eCRF as appropriate. ' answered with 'updated- a cancerous "spot" on nose was removed' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 18:07:05
Data point term sent to Coder	System	26 Oct 2020 18:06:50
Coding entries removed.	(b) (4), (b) (6)	26 Oct 2020 18:06:42
User entered 'BASAL CELL CARCINOMA (SKIN CANCER)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:06:42
User opened query 'Per DM CLR: Only one medical condition/diagnosis should be entered per line. Please review and provide separate entries for each condition. Update eCRF as appropriate. '(Site from DM).	(b) (4), (b) (6)	21 Oct 2020 15:34:52
User coded data point as SOC: Surgical and medical procedures, HLG: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin lesion excisions, PT: Skin neoplasm excision, LLT: Basal cell carcinoma skin excision - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 19:32:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 19:32:46

US3632064

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:14:39

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	10 Sep 2020 15:33:19
User entered 'Basal Cell Carcinoma (Skin Cancer)- removed cancerous "spot" on nose'	(b) (4), (b) (6)	10 Sep 2020 15:32:51

US3632064

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '1 Jul 2020'	(b) (4), (b) (6)	10 Sep 2020 15:32:51

US3632064

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:32:51

US3632064

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:14:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 16:02:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 16:02:31
User entered 'No (N)' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	17 Sep 2020 16:02:31
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 15:32:51
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:32:51

US3632064

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:41:05
Signature has been broken.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:54:58
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '1 Jul 2020' reason for change: Data Entry Error	Kelly Likos (b) (4)	17 Sep 2020 16:02:31
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:32:51

US3632064

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:14:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:32:51

US3632064

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:14:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered 'Jul 2020'	System	10 Sep 2020 15:32:51

US3632064

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:14:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered '2020'	System	10 Sep 2020 15:32:51

US3632064

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered 'Jul 2020'	System	17 Sep 2020 16:02:31
User entered empty.	System	10 Sep 2020 15:32:51

US3632064

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered '2020'	System	17 Sep 2020 16:02:31
User entered empty.	System	10 Sep 2020 15:32:51

US3632064

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:14:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User closed query 'Per MM, please include the underlying condition that led to the procedure. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 11:18:42
Query 'Per MM, please include the underlying condition that led to the procedure. ' answered with 'Skin cancers were the underlying condition.' (Site from DM).	Isaac Perez (b) (4) (b) (4)	08 Oct 2020 19:54:51
User coded data point as SOC: Surgical and medical procedures, HLG: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin lesion excisions, PT: Skin neoplasm excision, LLT: Skin cancer excision - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 18:53:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 18:53:30
User opened query 'Per MM, please include the underlying condition that led to the procedure. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 13:30:32
Data point term sent to Coder	System	10 Sep 2020 15:34:21
User entered 'Skin Cancer Cells Have been Removed- 6 different procedures in 30 years period (2 were Melanoma and the rest were BCC)'	(b) (4), (b) (6)	10 Sep 2020 15:33:42

US3632064

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '1 UNK 1990'	(b) (4), (b) (6)	10 Sep 2020 15:33:42

US3632064

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:33:42

US3632064

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:14:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:30:14
User closed query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 10:11:41
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	26 Oct 2020 18:06:10
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' answered with '6 Different procedures in 20 year period' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 18:05:58
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	26 Oct 2020 18:05:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:05:39
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 05:15:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 15:33:42

US3632064

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:33:42

US3632064

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:14:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:06:10
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:33:42

US3632064

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:14:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered 'Jan 1990'	System	10 Sep 2020 15:33:42

US3632064

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:14:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered '1990'	System	10 Sep 2020 15:33:42

US3632064

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered empty.	System	10 Sep 2020 15:33:42

US3632064

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered empty.	System	10 Sep 2020 15:33:42

US3632064

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:14:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User coded data point as SOC: Surgical and medical procedures, HLG: Endocrine gland therapeutic procedures, HLT: Thyroid therapeutic procedures, PT: Thyroidectomy, LLT: Thyroidectomy partial - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 10:08:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 10:08:56
Data point term sent to Coder	System	18 Nov 2020 14:43:18
Coding entries removed.	Aastha KC (b) (4) (b) (4)	18 Nov 2020 14:43:12
User entered 'THYROID GLAND Removed (PARTIAL REMOVAL)' reason for change: Data Entry Error	Aastha KC (b) (4) (b) (4)	18 Nov 2020 14:43:12
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 04:46:31
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:07:17
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 15:35:16
User coded data point as SOC: Surgical and medical procedures, HLG: Endocrine gland therapeutic procedures, HLT: Thyroid therapeutic procedures, PT: Thyroidectomy, LLT: Thyroidectomy partial - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 07:57:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 07:57:49

US3632064

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:14:39

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	10 Sep 2020 15:34:22
User entered 'Thyroid Gland Removal (partial removal)'	(b) (4), (b) (6)	10 Sep 2020 15:33:59

US3632064

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '1 UNK 2015'	(b) (4), (b) (6)	10 Sep 2020 15:33:59

US3632064

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:33:59

US3632064

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:14:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 16:42:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 16:42:21
User entered 'No (N)' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	17 Sep 2020 16:42:21
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 15:33:59
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:33:59

US3632064

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '1 UNK 2015' reason for change: Data Entry Error	Kelly Likos (b) (4)	17 Sep 2020 16:42:21
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:33:59

US3632064

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:14:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:33:59

US3632064

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:14:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered 'Jan 2015'	System	10 Sep 2020 15:33:59

US3632064

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:14:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered '2015'	System	10 Sep 2020 15:33:59

US3632064

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered 'Jan 2015'	System	17 Sep 2020 16:42:21
User entered empty.	System	10 Sep 2020 15:33:59

US3632064

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered '2015'	System	17 Sep 2020 16:42:21
User entered empty.	System	10 Sep 2020 15:33:59

US3632064

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:14:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLG: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Skin cancer, LLT: Skin cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 13:25:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 13:25:37
Data point term sent to Coder	System	10 Sep 2020 15:35:23
User entered 'Skin Cancer- monitored every 6 months'	(b) (4), (b) (6)	10 Sep 2020 15:34:29

US3632064

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '1 UNK 1990'	(b) (4), (b) (6)	10 Sep 2020 15:34:29

US3632064

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:34:29

US3632064

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:14:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 15:34:29

US3632064

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:34:29

US3632064

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:14:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:34:29

US3632064

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:14:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered 'Jan 1990'	System	10 Sep 2020 15:34:29

US3632064

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:14:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered '1990'	System	10 Sep 2020 15:34:29

US3632064

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered empty.	System	10 Sep 2020 15:34:29

US3632064

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered empty.	System	10 Sep 2020 15:34:29

US3632064

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:14:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User coded data point as SOC: Nervous system disorders, HLG: Movement disorders (incl parkinsonism), HLT: Parkinson's disease and parkinsonism, PT: Parkinson's disease, LLT: Parkinson's disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 15:19:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 15:19:07
Data point term sent to Coder	System	18 Nov 2020 14:49:22
Coding entries removed.	Aastha KC (b) (4) (b) (4)	18 Nov 2020 14:48:23
User entered 'PARKINSON'S DISEASE (Slow progression)' reason for change: Data Entry Error	Aastha KC (b) (4) (b) (4)	18 Nov 2020 14:48:23
User coded data point as SOC: Nervous system disorders, HLG: Movement disorders (incl parkinsonism), HLT: Parkinson's disease and parkinsonism, PT: Parkinson's disease, LLT: Parkinson's disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:37:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:37:28
Data point term sent to Coder	System	10 Sep 2020 15:35:25
User entered 'Parkinson's Disease'	(b) (4), (b) (6)	10 Sep 2020 15:34:41

US3632064

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '1 UNK 2019'	(b) (4), (b) (6)	10 Sep 2020 15:34:41

US3632064

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:34:41

US3632064

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:14:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 15:34:41

US3632064

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:34:41

US3632064

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:14:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:34:41

US3632064

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:14:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered 'Jan 2019'	System	10 Sep 2020 15:34:41

US3632064

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:14:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered '2019'	System	10 Sep 2020 15:34:41

US3632064

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered empty.	System	10 Sep 2020 15:34:41

US3632064

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered empty.	System	10 Sep 2020 15:34:41

US3632064

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:14:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Blood pressure high - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:37:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:37:30
Data point term sent to Coder	System	10 Sep 2020 15:35:26
User entered 'High Blood Pressure'	(b) (4), (b) (6)	10 Sep 2020 15:34:54

US3632064

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '1 UNK 1995'	(b) (4), (b) (6)	10 Sep 2020 15:34:54

US3632064

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:34:54

US3632064

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:14:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 15:34:54

US3632064

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:34:54

US3632064

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:14:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:34:54

US3632064

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:14:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered 'Jan 1995'	System	10 Sep 2020 15:34:54

US3632064

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:14:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered '1995'	System	10 Sep 2020 15:34:54

US3632064

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered empty.	System	10 Sep 2020 15:34:54

US3632064

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered empty.	System	10 Sep 2020 15:34:54

US3632064

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:14:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User coded data point as SOC: Investigations, HLGT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:37:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:37:28
Data point term sent to Coder	System	10 Sep 2020 15:35:26
User entered 'High Cholesterol'	(b) (4), (b) (6)	10 Sep 2020 15:35:06

US3632064

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '1 UNK 1995'	(b) (4), (b) (6)	10 Sep 2020 15:35:06

US3632064

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:35:06

US3632064

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:14:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 15:35:06

US3632064

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:35:06

US3632064

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:14:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:35:06

US3632064

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:14:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered 'Jan 1995'	System	10 Sep 2020 15:35:06

US3632064

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:14:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered '1995'	System	10 Sep 2020 15:35:06

US3632064

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered empty.	System	10 Sep 2020 15:35:06

US3632064

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered empty.	System	10 Sep 2020 15:35:06

US3632064

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:14:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:16:49
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
User coded data point as SOC: Reproductive system and breast disorders, HLG: 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)	30 Mar 2021 10:17:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	30 Mar 2021 10:17:21
User closed query 'Per MM: Please expand the abbreviation.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 05:14:29
Query 'Per MM: Please expand the abbreviation.' answered with 'expanded' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 16:51:32
Data point term sent to Coder	System	29 Mar 2021 16:51:03
Coding entries removed.	(b) (4), (b) (6)	29 Mar 2021 16:50:58
Signature has been broken.	(b) (4), (b) (6)	29 Mar 2021 16:50:58
User entered 'Benign Prostatic Hyperplasia (BPH) reason for change: Per Query Resolution	(b) (4), (b) (6)	29 Mar 2021 16:50:58
User opened query 'Per MM: Please expand the abbreviation.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 16:07:55
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
User closed query 'For coding purposes, please specify what the Prostate Issue is and update the term with your response' (Site from Coder).	(b) (4), (b) (6)	08 Mar 2021 15:50:11
User coded data point as SOC: Reproductive system and breast disorders, HLG: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: BPH - version MedDRA\23.0.	Coder Import (b) (4)	04 Feb 2021 21:35:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Feb 2021 21:35:27
Data point term sent to Coder	System	04 Feb 2021 21:35:20

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Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:14:39

Condition

Audit	User	Time (GMT)
Query 'For coding purposes, please specify what the Prostate Issue is and update the term with your response' answered with 'corrected' (Site from Coder). Coding entries removed.	(b) (4), (b) (6)	04 Feb 2021 21:34:54
User entered 'BPH' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Feb 2021 21:34:48
User opened query 'For coding purposes, please specify what the Prostate Issue is and update the term with your response' (Site from Coder).	(b) (4), (b) (6)	28 Jan 2021 19:49:00
User closed query 'For coding purposes, please split PROSTATE AND BLADDER ISSUES into separate entries and specify the issue for each.' (Site from Coder).	(b) (4), (b) (6)	28 Jan 2021 19:48:17
User coded data point as SOC: Reproductive system and breast disorders, HLG: Prostatic disorders (excl infections and inflammations), HLT: Prostatic signs, symptoms and disorders NEC, PT: Prostatic disorder, LLT: Prostatic disorder - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Jan 2021 19:52:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Jan 2021 19:52:31
Query 'For coding purposes, please split PROSTATE AND BLADDER ISSUES into separate entries and specify the issue for each.' answered with 'Entries Separated' (Site from Coder).	Isaac Perez (b) (4) (b) (4)	05 Jan 2021 19:36:23
Data point term sent to Coder	System	05 Jan 2021 19:36:13
Coding entries removed.	Isaac Perez (b) (4) (b) (4)	05 Jan 2021 19:36:09
User entered 'PROSTATE ISSUES' reason for change: Data Entry Error	Isaac Perez (b) (4) (b) (4)	05 Jan 2021 19:36:09
User coded data point as SOC: Reproductive system and breast disorders, HLG: Prostatic disorders (excl infections and inflammations), HLT: Prostatic signs, symptoms and disorders NEC, PT: Prostatic disorder, LLT: Prostatic disorder - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:56:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:56:54
User opened query 'For coding purposes, please split PROSTATE AND BLADDER ISSUES into separate entries and specify the issue for each.' (Site from Coder).	(b) (4), (b) (6)	18 Dec 2020 17:19:45

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Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:14:39

Condition

Audit	User	Time (GMT)
Data point term sent to Coder DataPoint Un-verified.	System (b) (4), (b) (6)	18 Dec 2020 16:22:11 18 Dec 2020 16:21:15
Coding entries removed.	(b) (4), (b) (6)	18 Dec 2020 16:21:15
User entered 'PROSTATE AND BLADDER ISSUES' reason for change: Data Entry Error DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Dec 2020 16:21:15 17 Dec 2020 17:30:14
User coded data point as SOC: Reproductive system and breast disorders, HLG: Prostatic disorders (excl infections and inflammations), HLT: Prostatic signs, symptoms and disorders NEC, PT: Prostatic disorder, LLT: Prostatic disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Nov 2020 18:13:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Nov 2020 18:13:59
Data point term sent to Coder	System	30 Nov 2020 18:13:05
User closed query 'DM-Coding: please split the term and report all the events on a separate line with all relevant information. 1) PROSTATE ISSUES 2)BLADDER ISSUES.' (Site from System).	System	30 Nov 2020 18:12:42
Query 'DM-Coding: please split the term and report all the events on a separate line with all relevant information. 1) PROSTATE ISSUES 2)BLADDER ISSUES.' answered with 'UPDATED' (Site from System).	Kelly Likos (b) (4) (b) (4)	30 Nov 2020 18:12:42
User entered 'PROSTATE ISSUES' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	30 Nov 2020 18:12:36
User opened query 'DM-Coding: please split the term and report all the events on a separate line with all relevant information. 1) PROSTATE ISSUES 2)BLADDER ISSUES.' (Site from System).	Coder Import (b) (4) (b) (4)	24 Nov 2020 13:18:22
User closed query 'Per DM CLR: Please specify or define what conditions are present in prostate and bladder. Update Med History eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 04:46:59
Query 'Per DM CLR: Please specify or define what conditions are present in prostate and bladder. Update Med History eCRF as appropriate.' answered with 'Participant only describes it as needing to use the restroom urgently' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:09:01

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Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:14:39

[Condition](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please specify or define what conditions are present in prostate and bladder. Update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 05:16:44
Data point term sent to Coder	System	10 Sep 2020 15:35:26
User entered 'Prostate and Bladder Issues'	(b) (4), (b) (6)	10 Sep 2020 15:35:18

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Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '1 UNK 2018'	(b) (4), (b) (6)	10 Sep 2020 15:35:18

US3632064

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:35:18

US3632064

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:14:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 15:35:18

US3632064

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:35:18

US3632064

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:14:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:35:18

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Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:14:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered 'Jan 2018'	System	10 Sep 2020 15:35:18

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Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:14:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered '2018'	System	10 Sep 2020 15:35:18

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Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered empty.	System	10 Sep 2020 15:35:18

US3632064

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered empty.	System	10 Sep 2020 15:35:18

US3632064

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:14:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Rosaceas, PT: Rosacea, LLT: Rosacea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:37:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:37:48
Data point term sent to Coder	System	10 Sep 2020 15:36:27
User entered 'Rosacea '	(b) (4), (b) (6)	10 Sep 2020 15:35:40

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Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '1 UNK 1990'	(b) (4), (b) (6)	10 Sep 2020 15:35:40

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Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:35:40

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Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:14:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 15:35:40

US3632064

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:35:40

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Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:14:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:35:40

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Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:14:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered 'Jan 1990'	System	10 Sep 2020 15:35:40

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Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:14:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered '1990'	System	10 Sep 2020 15:35:40

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Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered empty.	System	10 Sep 2020 15:35:40

US3632064

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered empty.	System	10 Sep 2020 15:35:40

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Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:14:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 09:32:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 09:32:13
Data point term sent to Coder	System	17 Sep 2020 16:54:04
User entered 'SEVERE OBESITY WITH A BMI OVER 40'	Kelly Likos (b) (4) (b) (4)	17 Sep 2020 16:53:42

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Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '1 UNK 2020'	Kelly Likos (b) (4) (b) (4)	17 Sep 2020 16:53:42

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Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '0'	Kelly Likos (b) (4) (b) (4)	17 Sep 2020 16:53:42

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Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:14:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	17 Sep 2020 16:53:42

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Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered empty.	Kelly Likos (b) (4) (b) (4)	17 Sep 2020 16:53:42

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Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:14:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '0'	Kelly Likos (b) (4) (b) (4)	17 Sep 2020 16:53:42

US3632064

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:14:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered 'Jan 2020'	System	17 Sep 2020 16:53:42

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Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:14:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered '2020'	System	17 Sep 2020 16:53:42

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Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered empty.	System	17 Sep 2020 16:53:42

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Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered empty.	System	17 Sep 2020 16:53:42

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Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:14:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User coded data point as SOC: Endocrine disorders, HLG: Thyroid gland disorders, HLT: Thyroid disorders NEC, PT: Thyroid mass, LLT: Thyroid nodule - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 10:08:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 10:08:03
Data point term sent to Coder	System	18 Nov 2020 14:48:21
Coding entries removed.	Aastha KC (b) (4) (b) (4)	18 Nov 2020 14:47:21
User entered 'THYROID NODULES (Resulted in a partial thyroid removal)' reason for change: Data Entry Error	Aastha KC (b) (4) (b) (4)	18 Nov 2020 14:47:21
User coded data point as SOC: Endocrine disorders, HLG: Thyroid gland disorders, HLT: Thyroid disorders NEC, PT: Thyroid mass, LLT: Thyroid nodule - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 18:36:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 18:36:18
Data point term sent to Coder	System	28 Oct 2020 16:08:17
User entered 'Thyroid Nodules'	(b) (4), (b) (6)	28 Oct 2020 16:07:38

US3632064

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '1 UNK 2015'	(b) (4), (b) (6)	28 Oct 2020 16:07:38

US3632064

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 16:07:38

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Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:14:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 16:07:38

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Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '1 UNK 2015'	(b) (4), (b) (6)	28 Oct 2020 16:07:38

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Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:14:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:30:14
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 16:07:38

US3632064

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:14:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered 'Jan 2015'	System	28 Oct 2020 16:07:38

US3632064

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:14:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered '2015'	System	28 Oct 2020 16:07:38

US3632064

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered 'Jan 2015'	System	28 Oct 2020 16:07:38

US3632064

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered '2015'	System	28 Oct 2020 16:07:38

US3632064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:31:41
User entered 'Yes (Y)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 20:58:37

US3632064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:31:41
User entered '09 Sep 2020'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 20:58:37

US3632064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:31:41
User entered '13:44' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 15:29:05
User entered '12:00'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 20:58:37

US3632064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered '09 Sep 2020 13:44'	System	10 Sep 2020 15:29:05
User entered '09 Sep 2020 12:00'	System	09 Sep 2020 20:58:37

US3632064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:31:41
User entered '68' in	Bezuayehu Mandefro (b) (4)	09 Sep 2020 20:58:37
DataPoint set to visible.	System	09 Sep 2020 19:17:31

US3632064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:31:41
User entered '267.2' lb	Bezuayehu Mandefro (b) (4)	09 Sep 2020 20:58:37
DataPoint set to visible.	System	09 Sep 2020 19:17:31

US3632064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User closed query 'Per CDM: Please confirm if Height and Weight values are correct. BMI suggests patient has Severe Obesity. If so, please update Medical History. Thank you' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 06:29:23
Query 'Per CDM: Please confirm if Height and Weight values are correct. BMI suggests patient has Severe Obesity. If so, please update Medical History. Thank you' answered with 'MEDICAL HISTORY UPDATED' (Site from DM).	Kelly Likos (b) (4) (b) (4)	17 Sep 2020 16:55:31
User opened query 'Per CDM: Please confirm if Height and Weight values are correct. BMI suggests patient has Severe Obesity. If so, please update Medical History. Thank you' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 19:35:16
User entered '40.71257'	System	09 Sep 2020 20:58:37
DataPoint set to visible.	System	09 Sep 2020 19:17:31

US3632064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered 'kg/m2'	System	09 Sep 2020 20:58:37
DataPoint set to visible.	System	09 Sep 2020 19:17:31

US3632064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:31:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 14:47:59
User entered '97.1' F	Bezuayehu Mandefro (b) (4)	09 Sep 2020 20:58:37

US3632064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:31:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 14:47:59
User entered 'Oral (Oral)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 20:58:37

US3632064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:31:41
User entered empty.	Bezuayehu Mandefro (b) (4)	09 Sep 2020 20:58:37

US3632064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:31:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 14:47:59
User entered '45'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 20:58:37

US3632064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered 'bpm'	System	09 Sep 2020 20:58:37

US3632064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:31:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 14:47:59
User entered '16'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 20:58:37

US3632064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered 'breaths/min'	System	09 Sep 2020 20:58:37

US3632064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:31:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 14:47:59
User entered '138'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 20:58:37

US3632064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered 'mmHg'	System	09 Sep 2020 20:58:37

US3632064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:31:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 14:47:59
User entered '73'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 20:58:37

US3632064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered 'mmHg'	System	09 Sep 2020 20:58:37

US3632064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45

US3632064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45

US3632064

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:14:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:34:05
User entered 'Yes (Y)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 20:58:48

US3632064

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:14:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:34:05
User entered '09 Sep 2020'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 20:58:48

US3632064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:34:42
User entered 'No (N)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:00:02

US3632064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:34:42
User entered 'No (N)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:00:02

US3632064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:34:42
User entered 'No (N)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:00:02

US3632064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:34:42
User entered 'No (N)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:00:02

US3632064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:34:42
User entered 'No (N)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:00:02

US3632064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:34:42
User entered 'No (N)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:00:02

US3632064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:34:42
User entered 'No (N)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:00:02

US3632064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:34:42
User entered 'No (N)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:00:02

US3632064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:34:42
User entered 'No (N)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:00:02

US3632064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:34:42
User entered 'No (N)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:00:02

US3632064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:34:42
User entered 'No (N)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:00:02

US3632064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:39

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:34:42
User entered 'Yes (Y)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:00:02

US3632064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:39

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:34:42
User entered 'GOEs to grocery store' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 15:29:27
User entered 'Goes Grocery Shopping'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:00:02

US3632064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:39

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
User entered '1'	(b) (4) Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:00:02

US3632064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:39

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:34:42
User entered '0'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:00:02

US3632064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:34:42
User entered '0'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:00:02

US3632064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:34:42
User entered '0'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:00:02

US3632064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:34:42
User entered '0'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:00:02

US3632064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:34:42
User entered '0'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:00:02

US3632064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:39

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
User entered '0'	(b) (4) Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:00:02

US3632064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:39

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:21:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:34:42
User entered empty.	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:00:02

US3632064

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:14:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:35:02
User entered 'Yes (Y)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 19:33:59

US3632064

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:35:02
User entered '09 Sep 2020'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 19:33:59

US3632064

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:35:02
User entered 'Clinic (Clinic)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 19:33:59

US3632064

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:14:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered 'VISIT1'	System	09 Sep 2020 19:33:59

US3632064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:35:59
User entered '09 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 18:19:46

US3632064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:35:59
User entered '190035'	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 18:19:46

US3632064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:35:59
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 18:19:46

US3632064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:35:59
User entered 'No (N)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 19:34:21

US3632064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:35:59
User entered 'No (N)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 19:34:21

US3632064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:35:59
User entered 'Yes (Y)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 19:34:21

US3632064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:14:39

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:35:59
User entered 'No (N)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 19:34:21

US3632064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:14:39

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:35:59
User entered 'No (N)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 19:34:21

US3632064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:14:39

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:35:59
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 05:43:29
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'Updated field.' (Site from DM).	Isaac Perez (b) (4) (b) (4)	08 Dec 2020 14:04:38
User entered 'No (N)'	Isaac Perez (b) (4) (b) (4)	08 Dec 2020 14:04:34
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 22:20:27
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:49:56
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:49:55

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:14:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:38:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 14:47:41
User entered '68' in	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:14:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:38:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 14:47:41
User entered '267.2' lb	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:14:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:38:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 14:47:41
User entered '68' in	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:14:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:38:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 14:47:41
User entered '267.2' lb	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User accepted default value 'Pre-Dose (PREDOSE)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:38:17
User entered 'Yes (Y)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:39

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:38:17
User entered '09 Sep 2020'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:38:17
User entered '13:44'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered '09 Sep 2020 13:44'	System	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:38:17
User entered '97.1' F	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:38:17
User entered 'Oral (Oral)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:38:17
User entered empty.	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:38:17
User entered '45'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered 'bpm'	System	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:38:17
User entered '16'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered 'breaths/min'	System	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:38:17
User entered '138'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered 'mmHg'	System	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:38:17
User entered '73'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered 'mmHg'	System	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:14:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:38:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 14:47:41
User entered '68' in	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:14:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:38:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 14:47:41
User entered '267.2' lb	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User accepted default value 'Post-Dose (POSTDOSE)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:38:17
User entered 'Yes (Y)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:39

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:38:17
User entered '09 Sep 2020'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:38:17
User entered '15:57'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered '09 Sep 2020 15:57'	System	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:38:17
User entered '96.8' F	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:38:17
User entered 'Oral (Oral)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:38:17
User entered empty.	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:38:17
User entered '45'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered 'bpm'	System	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:38:17
User entered '18'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered 'breaths/min'	System	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:38:17
User entered '137'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered 'mmHg'	System	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:38:17
User entered '73'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered 'mmHg'	System	09 Sep 2020 21:10:40

US3632064

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:14:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:38:48
User entered 'Yes (Y)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:10:55

US3632064

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:14:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:38:48
User entered '09 Sep 2020'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:10:55

US3632064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:14:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:38:53
User entered 'Yes (Y)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 19:35:08

US3632064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:14:39

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:38:53
User entered empty.	Bezuayehu Mandefro (b) (4)	09 Sep 2020 19:35:08

US3632064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:38:53
User entered empty.	Bezuayehu Mandefro (b) (4)	09 Sep 2020 19:35:08

US3632064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:14:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered 'MRNA-1273 OR PLACEBO'	System	09 Sep 2020 19:35:08

US3632064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:14:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:38:53
User entered '09 Sep 2020'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 19:35:08

US3632064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:38:53
User entered '15:14'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 19:35:08

US3632064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered '09 Sep 2020 15:14'	System	09 Sep 2020 19:35:08

US3632064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:38:53
User entered 'Left Arm (LEFT ARM)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 19:35:08

US3632064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:38:53
User entered 'ONCE'	System	09 Sep 2020 19:35:08

US3632064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:14:39

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered 'INTRAMUSCULAR'	System	09 Sep 2020 19:35:08

US3632064

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:39:14
User entered 'Yes (Y)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:11:16

US3632064

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:39:14
User entered '09 Sep 2020'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:11:16

US3632064

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:39:14
User entered '14:20'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:11:16

US3632064

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered '09 Sep 2020 14:20'	System	09 Sep 2020 21:11:16

US3632064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:14:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:39:27
User entered '09 Sep 2020'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:11:34

US3632064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:14:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:11:34

US3632064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:14:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:39:27
User entered 'Yes (Y)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:11:34

US3632064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:14:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:39:27
User entered '14:26' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 15:31:10
User entered '14:20'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:11:34

US3632064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered '09 Sep 2020 14:26'	System	10 Sep 2020 15:31:10
User entered '09 Sep 2020 14:20'	System	09 Sep 2020 21:11:34

US3632064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:14:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:11:34

US3632064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:14:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:39:27
User entered 'No (N)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:11:34

US3632064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:14:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:39:27
User entered empty.	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:11:34

US3632064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered empty.	System	09 Sep 2020 21:11:34

US3632064

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:39:35
User entered 'Yes (Y)'	Bezuayehu Mandefro (b) (4)	09 Sep 2020 21:11:39

US3632064

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:14:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered '1'	System	09 Sep 2020 21:11:39

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	09 Sep 2020 19:35:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-09T15:59:36', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '03467f1a-b96f-4a2c-82b7-a99d772f9018'	System	09 Sep 2020 20:00:17
User entered 'Yes (Y)'	System	09 Sep 2020 20:00:17

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-09T15:59:54', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '03467f1a-b96f-4a2c-82b7-a99d772f9018' User entered '96.8'	System	09 Sep 2020 20:00:17
	System	09 Sep 2020 20:00:17

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-09T16:00:01', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '03467f1a-b96f-4a2c-82b7-a99d772f9018'	System	09 Sep 2020 20:00:17
User entered 'No (N)'	System	09 Sep 2020 20:00:17

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-09T16:00:15', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '03467f1a-b96f-4a2c-82b7-a99d772f9018' User entered '09 Sep 2020 16:00'	System	09 Sep 2020 20:00:17
	System	09 Sep 2020 20:00:17

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '09 Sep 2020 15:34'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '09 Sep 2020 18:04'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	09 Sep 2020 19:35:08
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-09T22:47:59', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '2cac5983-641e-4661-a0cf-8daff63df137'	System	10 Sep 2020 02:48:35
User entered 'Yes (Y)'	System	10 Sep 2020 02:48:35

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-09T22:48:09', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '2cac5983-641e-4661-a0cf-8daff63df137' User entered '97.3'	System	10 Sep 2020 02:48:35
	System	10 Sep 2020 02:48:35

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-09T22:48:17', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '2cac5983-641e-4661-a0cf-8daff63df137'	System	10 Sep 2020 02:48:35
User entered 'No (N)'	System	10 Sep 2020 02:48:35

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-09T22:48:31', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '2cac5983-641e-4661-a0cf-8daff63df137' User entered '09 Sep 2020 22:48'	System	10 Sep 2020 02:48:35
	System	10 Sep 2020 02:48:35

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '09 Sep 2020 18:59'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	09 Sep 2020 19:35:08
User entered 'Day 2'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-10T22:38:50', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '2ea66228-7efe-4287-b7cb-d5109adff7d7'	System	11 Sep 2020 02:39:37
User entered 'Yes (Y)'	System	11 Sep 2020 02:39:37

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-10T22:39:03', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '2ea66228-7efe-4287-b7cb-d5109adff7d7'	System	11 Sep 2020 02:39:37
User entered '97.4'	System	11 Sep 2020 02:39:37

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-10T22:39:13', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '2ea66228-7efe-4287-b7cb-d5109adff7d7'	System	11 Sep 2020 02:39:37
User entered 'No (N)'	System	11 Sep 2020 02:39:37

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-10T22:39:35', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '2ea66228-7efe-4287-b7cb-d5109adff7d7'	System	11 Sep 2020 02:39:37
User entered '10 Sep 2020 22:39'	System	11 Sep 2020 02:39:37

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	09 Sep 2020 19:35:08
User entered 'Day 3'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-11T22:21:52', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '801f37f8-93d2-4cb6-88a2-f31420870a66'	System	12 Sep 2020 02:27:19
User entered 'Yes (Y)'	System	12 Sep 2020 02:27:19

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-11T22:22:08', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '801f37f8-93d2-4cb6-88a2-f31420870a66' User entered '97.4'	System	12 Sep 2020 02:27:19
	System	12 Sep 2020 02:27:19

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-11T22:22:16', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '801f37f8-93d2-4cb6-88a2-f31420870a66'	System	12 Sep 2020 02:27:19
User entered 'No (N)'	System	12 Sep 2020 02:27:19

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-11T22:22:29', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '801f37f8-93d2-4cb6-88a2-f31420870a66'	System	12 Sep 2020 02:27:19
User entered '11 Sep 2020 22:22'	System	12 Sep 2020 02:27:19

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	09 Sep 2020 19:35:08
User entered 'Day 4'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-12T22:18:05', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'b1c73b36-651c-445e-9690-c5f6321586d9' User entered 'Yes (Y)'	System	13 Sep 2020 02:18:57
	System	13 Sep 2020 02:18:57

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-12T22:18:38', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'b1c73b36-651c-445e-9690-c5f6321586d9' User entered '97.8'	System	13 Sep 2020 02:18:57
	System	13 Sep 2020 02:18:57

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-12T22:18:45', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'b1c73b36-651c-445e-9690-c5f6321586d9' User entered 'No (N)'	System	13 Sep 2020 02:18:57
	System	13 Sep 2020 02:18:57

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-12T22:18:54', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'b1c73b36-651c-445e-9690-c5f6321586d9' User entered '12 Sep 2020 22:18'	System	13 Sep 2020 02:18:57
	System	13 Sep 2020 02:18:57

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	09 Sep 2020 19:35:08
User entered 'Day 5'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-13T22:33:33', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '1adc75ab-c413-45d5-b416-ca32481fd767' User entered 'Yes (Y)'	System	14 Sep 2020 02:34:30
	System	14 Sep 2020 02:34:30

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-13T22:34:07', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '1adc75ab-c413-45d5-b416-ca32481fd767' User entered '97.6'	System	14 Sep 2020 02:34:30
	System	14 Sep 2020 02:34:30

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-13T22:34:16', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '1adc75ab-c413-45d5-b416-ca32481fd767'	System	14 Sep 2020 02:34:30
User entered 'No (N)'	System	14 Sep 2020 02:34:30

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-13T22:34:26', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '1adc75ab-c413-45d5-b416-ca32481fd767' User entered '13 Sep 2020 22:34'	System	14 Sep 2020 02:34:30
	System	14 Sep 2020 02:34:30

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	09 Sep 2020 19:35:08
User entered 'Day 6'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-14T21:56:34', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '9c6435fd-25cb-4ed3-8db9-c6bc60cada4c' User entered 'Yes (Y)'	System	15 Sep 2020 01:57:44
	System	15 Sep 2020 01:57:44

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-14T21:57:07', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '9c6435fd-25cb-4ed3-8db9-c6bc60cada4c' User entered '97.6'	System	15 Sep 2020 01:57:44
	System	15 Sep 2020 01:57:44

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-14T21:57:28', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '9c6435fd-25cb-4ed3-8db9-c6bc60cada4c' User entered 'No (N)'	System	15 Sep 2020 01:57:44
	System	15 Sep 2020 01:57:44

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-14T21:57:40', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '9c6435fd-25cb-4ed3-8db9-c6bc60cada4c' User entered '14 Sep 2020 21:57'	System	15 Sep 2020 01:57:44
	System	15 Sep 2020 01:57:44

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	09 Sep 2020 19:35:08
User entered 'Day 7'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-15T21:55:49', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '63e789a3-7e0a-429c-95c6-fac43a74816e' User entered 'Yes (Y)'	System	16 Sep 2020 01:56:21
	System	16 Sep 2020 01:56:21

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-15T21:56:02', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '63e789a3-7e0a-429c-95c6-fac43a74816e' User entered '97.6'	System	16 Sep 2020 01:56:21
	System	16 Sep 2020 01:56:21

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-15T21:56:09', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '63e789a3-7e0a-429c-95c6-fac43a74816e' User entered 'No (N)'	System	16 Sep 2020 01:56:21
	System	16 Sep 2020 01:56:21

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-15T21:56:20', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '63e789a3-7e0a-429c-95c6-fac43a74816e' User entered '15 Sep 2020 21:56'	System	16 Sep 2020 01:56:21
	System	16 Sep 2020 01:56:21

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	09 Sep 2020 19:35:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-09T16:00:31', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '73ffe0bf-e293-4ee0-82bc-4bb70256760c'	System	09 Sep 2020 20:02:53
User entered 'None (1)'	System	09 Sep 2020 20:02:53

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-09T16:00:37', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '73ffe0bf-e293-4ee0-82bc-4bb70256760c' User entered 'No (N)'	System	09 Sep 2020 20:02:53
	System	09 Sep 2020 20:02:53

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-09T16:00:43', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '73ffe0bf-e293-4ee0-82bc-4bb70256760c' User entered 'No (N)'	System	09 Sep 2020 20:02:53
	System	09 Sep 2020 20:02:53

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-09T16:02:07', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '73ffe0bf-e293-4ee0-82bc-4bb70256760c'	System	09 Sep 2020 20:02:53
User entered 'None (1)'	System	09 Sep 2020 20:02:53

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-09T16:02:51', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '73ffe0bf-e293-4ee0-82bc-4bb70256760c' User entered '09 Sep 2020 16:02'	System	09 Sep 2020 20:02:53
	System	09 Sep 2020 20:02:53

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '09 Sep 2020 15:34'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '09 Sep 2020 18:04'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	09 Sep 2020 19:35:08
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-09T22:48:46', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '5514fbad-7725-4122-863e-9cb2a80b3ad2'	System	10 Sep 2020 02:49:25
User entered 'None (1)'	System	10 Sep 2020 02:49:25

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-09T22:48:56', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '5514fbad-7725-4122-863e-9cb2a80b3ad2'	System	10 Sep 2020 02:49:25
User entered 'No (N)'	System	10 Sep 2020 02:49:25

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-09T22:49:01', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '5514fbad-7725-4122-863e-9cb2a80b3ad2'	System	10 Sep 2020 02:49:25
User entered 'No (N)'	System	10 Sep 2020 02:49:25

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-09T22:49:11', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '5514fbad-7725-4122-863e-9cb2a80b3ad2'	System	10 Sep 2020 02:49:25
User entered 'None (1)'	System	10 Sep 2020 02:49:25

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-09T22:49:23', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '5514fbad-7725-4122-863e-9cb2a80b3ad2'	System	10 Sep 2020 02:49:25
User entered '09 Sep 2020 22:49'	System	10 Sep 2020 02:49:25

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '09 Sep 2020 18:59'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	09 Sep 2020 19:35:08
User entered 'Day 2'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-10T22:39:59', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '1cf10802-2156-46a4-a4ec-692cbdf24eb0'	System	11 Sep 2020 02:41:56
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 02:41:56

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-10T22:41:01', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '1cf10802-2156-46a4-a4ec-692cbdf24eb0'	System	11 Sep 2020 02:41:56
User entered 'No (N)'	System	11 Sep 2020 02:41:56

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-10T22:41:16', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '1cf10802-2156-46a4-a4ec-692cbdf24eb0'	System	11 Sep 2020 02:41:56
User entered 'No (N)'	System	11 Sep 2020 02:41:56

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-10T22:41:27', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '1cf10802-2156-46a4-a4ec-692cbdf24eb0'	System	11 Sep 2020 02:41:56
User entered 'None (1)'	System	11 Sep 2020 02:41:56

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-10T22:41:53', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '1cf10802-2156-46a4-a4ec-692cbdf24eb0' User entered '10 Sep 2020 22:41'	System	11 Sep 2020 02:41:56
	System	11 Sep 2020 02:41:56

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	09 Sep 2020 19:35:08
User entered 'Day 3'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-11T22:22:40', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '0aa7c97c-6394-445e-831f-d407aea554df'	System	12 Sep 2020 02:26:14
User entered 'None (1)'	System	12 Sep 2020 02:26:14

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-11T22:22:46', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '0aa7c97c-6394-445e-831f-d407aea554df' User entered 'No (N)'	System	12 Sep 2020 02:26:14
	System	12 Sep 2020 02:26:14

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-11T22:22:50', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '0aa7c97c-6394-445e-831f-d407aea554df' User entered 'No (N)'	System	12 Sep 2020 02:26:14
	System	12 Sep 2020 02:26:14

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-11T22:22:57', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '0aa7c97c-6394-445e-831f-d407aea554df'	System	12 Sep 2020 02:26:14
User entered 'None (1)'	System	12 Sep 2020 02:26:14

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-11T22:23:05', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '0aa7c97c-6394-445e-831f-d407aea554df' User entered '11 Sep 2020 22:23'	System	12 Sep 2020 02:26:14
	System	12 Sep 2020 02:26:14

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	09 Sep 2020 19:35:08
User entered 'Day 4'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-12T22:19:12', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'ff56f246-5b1a-4bb0-a515-289938b7a05c'	System	13 Sep 2020 02:19:45
User entered 'None (1)'	System	13 Sep 2020 02:19:45

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-12T22:19:17', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'ff56f246-5b1a-4bb0-a515-289938b7a05c' User entered 'No (N)'	System	13 Sep 2020 02:19:45
	System	13 Sep 2020 02:19:45

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-12T22:19:22', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'ff56f246-5b1a-4bb0-a515-289938b7a05c' User entered 'No (N)'	System	13 Sep 2020 02:19:45
	System	13 Sep 2020 02:19:45

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-12T22:19:28', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'ff56f246-5b1a-4bb0-a515-289938b7a05c' User entered 'None (1)'	System	13 Sep 2020 02:19:45
	System	13 Sep 2020 02:19:45

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-12T22:19:42', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'ff56f246-5b1a-4bb0-a515-289938b7a05c' User entered '12 Sep 2020 22:19'	System	13 Sep 2020 02:19:45
	System	13 Sep 2020 02:19:45

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	09 Sep 2020 19:35:08
User entered 'Day 5'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-13T22:34:50', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'b84468c6-f823-49f3-b956-b3611539a6d3'	System	14 Sep 2020 02:35:25
User entered 'None (1)'	System	14 Sep 2020 02:35:25

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-13T22:34:54', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'b84468c6-f823-49f3-b956-b3611539a6d3'	System	14 Sep 2020 02:35:25
User entered 'No (N)'	System	14 Sep 2020 02:35:25

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-13T22:34:59', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'b84468c6-f823-49f3-b956-b3611539a6d3' User entered 'No (N)'	System	14 Sep 2020 02:35:25
	System	14 Sep 2020 02:35:25

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-13T22:35:09', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'b84468c6-f823-49f3-b956-b3611539a6d3'	System	14 Sep 2020 02:35:25
User entered 'None (1)'	System	14 Sep 2020 02:35:25

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-13T22:35:23', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'b84468c6-f823-49f3-b956-b3611539a6d3' User entered '13 Sep 2020 22:35'	System	14 Sep 2020 02:35:25
	System	14 Sep 2020 02:35:25

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	09 Sep 2020 19:35:08
User entered 'Day 6'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-14T21:57:50', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '1b62f138-8786-4f74-859a-f73fbd6a3b26'	System	15 Sep 2020 01:58:16
User entered 'None (1)'	System	15 Sep 2020 01:58:16

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-14T21:57:55', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '1b62f138-8786-4f74-859a-f73fbd6a3b26'	System	15 Sep 2020 01:58:16
User entered 'No (N)'	System	15 Sep 2020 01:58:16

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-14T21:58:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '1b62f138-8786-4f74-859a-f73fbd6a3b26'	System	15 Sep 2020 01:58:16
User entered 'No (N)'	System	15 Sep 2020 01:58:16

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-14T21:58:05', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '1b62f138-8786-4f74-859a-f73fbd6a3b26'	System	15 Sep 2020 01:58:16
User entered 'None (1)'	System	15 Sep 2020 01:58:16

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-14T21:58:11', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '1b62f138-8786-4f74-859a-f73fbd6a3b26'	System	15 Sep 2020 01:58:16
User entered '14 Sep 2020 21:58'	System	15 Sep 2020 01:58:16

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	09 Sep 2020 19:35:08
User entered 'Day 7'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-15T21:56:38', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '5f3f2fe6-2e9e-493f-a010-c227f589d41c'	System	16 Sep 2020 01:57:08
User entered 'None (1)'	System	16 Sep 2020 01:57:08

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-15T21:56:44', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '5f3f2fe6-2e9e-493f-a010-c227f589d41c' User entered 'No (N)'	System	16 Sep 2020 01:57:08
	System	16 Sep 2020 01:57:08

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-15T21:56:51', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '5f3f2fe6-2e9e-493f-a010-c227f589d41c' User entered 'No (N)'	System	16 Sep 2020 01:57:08
	System	16 Sep 2020 01:57:08

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-15T21:56:58', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '5f3f2fe6-2e9e-493f-a010-c227f589d41c'	System	16 Sep 2020 01:57:08
User entered 'None (1)'	System	16 Sep 2020 01:57:08

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-15T21:57:06', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '5f3f2fe6-2e9e-493f-a010-c227f589d41c' User entered '15 Sep 2020 21:57'	System	16 Sep 2020 01:57:08
	System	16 Sep 2020 01:57:08

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	09 Sep 2020 19:35:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-09T16:03:07', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'afec5af0-ac4f-4842-9833-8337d2ca142c' User entered 'None (0)'	System	09 Sep 2020 20:04:07
	System	09 Sep 2020 20:04:07

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-09T16:03:11', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'afec5af0-ac4f-4842-9833-8337d2ca142c' User entered 'None (0)'	System	09 Sep 2020 20:04:07
	System	09 Sep 2020 20:04:07

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-09T16:03:16', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'afec5af0-ac4f-4842-9833-8337d2ca142c' User entered 'None (0)'	System	09 Sep 2020 20:04:07
	System	09 Sep 2020 20:04:07

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-09T16:03:21', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'afec5af0-ac4f-4842-9833-8337d2ca142c' User entered 'None (0)'	System	09 Sep 2020 20:04:07
	System	09 Sep 2020 20:04:07

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-09T16:03:25', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'afec5af0-ac4f-4842-9833-8337d2ca142c' User entered 'None (0)'	System	09 Sep 2020 20:04:07
	System	09 Sep 2020 20:04:07

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-09T16:03:31', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'afec5af0-ac4f-4842-9833-8337d2ca142c' User entered 'None (0)'	System	09 Sep 2020 20:04:07
	System	09 Sep 2020 20:04:07

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-09T16:03:37', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'afec5af0-ac4f-4842-9833-8337d2ca142c' User entered 'No (N)'	System	09 Sep 2020 20:04:07
	System	09 Sep 2020 20:04:07

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-09T16:04:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'afec5af0-ac4f-4842-9833-8337d2ca142c' User entered '09 Sep 2020 16:04'	System	09 Sep 2020 20:04:07
	System	09 Sep 2020 20:04:07

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '09 Sep 2020 15:34'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '09 Sep 2020 18:04'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	09 Sep 2020 19:35:08
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-09T22:49:36', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'dd231845-6ae3-4277-9667-0c048afa9c12' User entered 'None (0)'	System	10 Sep 2020 02:50:27
	System	10 Sep 2020 02:50:27

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-09T22:49:41', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'dd231845-6ae3-4277-9667-0c048afa9c12' User entered 'None (0)'	System	10 Sep 2020 02:50:27
	System	10 Sep 2020 02:50:27

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-09T22:49:45', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'dd231845-6ae3-4277-9667-0c048afa9c12'	System	10 Sep 2020 02:50:27
User entered 'None (0)'	System	10 Sep 2020 02:50:27

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-09T22:49:51', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'dd231845-6ae3-4277-9667-0c048afa9c12' User entered 'None (0)'	System	10 Sep 2020 02:50:27
	System	10 Sep 2020 02:50:27

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-09T22:49:56', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'dd231845-6ae3-4277-9667-0c048afa9c12'	System	10 Sep 2020 02:50:27
User entered 'None (0)'	System	10 Sep 2020 02:50:27

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-09T22:50:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'dd231845-6ae3-4277-9667-0c048afa9c12' User entered 'None (0)'	System	10 Sep 2020 02:50:27
	System	10 Sep 2020 02:50:27

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-09T22:50:10', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'dd231845-6ae3-4277-9667-0c048afa9c12'	System	10 Sep 2020 02:50:27
User entered 'No (N)'	System	10 Sep 2020 02:50:27

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-09T22:50:26', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'dd231845-6ae3-4277-9667-0c048afa9c12' User entered '09 Sep 2020 22:50'	System	10 Sep 2020 02:50:27
	System	10 Sep 2020 02:50:27

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '09 Sep 2020 18:59'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	09 Sep 2020 19:35:08
User entered 'Day 2'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-10T22:42:01', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '06a03d99-1fd2-4d92-b478-b743c21c23d4' User entered 'None (0)'	System	11 Sep 2020 02:42:53
	System	11 Sep 2020 02:42:53

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-10T22:42:05', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '06a03d99-1fd2-4d92-b478-b743c21c23d4' User entered 'None (0)'	System	11 Sep 2020 02:42:53
	System	11 Sep 2020 02:42:53

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-10T22:42:11', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '06a03d99-1fd2-4d92-b478-b743c21c23d4' User entered 'None (0)'	System	11 Sep 2020 02:42:53
	System	11 Sep 2020 02:42:53

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-10T22:42:17', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '06a03d99-1fd2-4d92-b478-b743c21c23d4' User entered 'None (0)'	System	11 Sep 2020 02:42:53
	System	11 Sep 2020 02:42:53

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-10T22:42:21', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '06a03d99-1fd2-4d92-b478-b743c21c23d4' User entered 'None (0)'	System	11 Sep 2020 02:42:53
	System	11 Sep 2020 02:42:53

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-10T22:42:25', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '06a03d99-1fd2-4d92-b478-b743c21c23d4' User entered 'None (0)'	System	11 Sep 2020 02:42:53
	System	11 Sep 2020 02:42:53

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-10T22:42:32', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '06a03d99-1fd2-4d92-b478-b743c21c23d4' User entered 'No (N)'	System	11 Sep 2020 02:42:53
	System	11 Sep 2020 02:42:53

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-10T22:42:50', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '06a03d99-1fd2-4d92-b478-b743c21c23d4' User entered '10 Sep 2020 22:42'	System	11 Sep 2020 02:42:53
	System	11 Sep 2020 02:42:53

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	09 Sep 2020 19:35:08
User entered 'Day 3'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-11T22:23:14', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'a7f42848-7a6d-47c1-ba43-af143a3a77a4'	System	12 Sep 2020 02:26:27
User entered 'None (0)'	System	12 Sep 2020 02:26:27

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-11T22:23:18', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'a7f42848-7a6d-47c1-ba43-af143a3a77a4' User entered 'None (0)'	System	12 Sep 2020 02:26:27
	System	12 Sep 2020 02:26:27

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-11T22:23:25', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'a7f42848-7a6d-47c1-ba43-af143a3a77a4'	System	12 Sep 2020 02:26:27
User entered 'None (0)'	System	12 Sep 2020 02:26:27

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-11T22:23:31', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'a7f42848-7a6d-47c1-ba43-af143a3a77a4' User entered 'None (0)'	System	12 Sep 2020 02:26:27
	System	12 Sep 2020 02:26:27

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-11T22:23:36', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'a7f42848-7a6d-47c1-ba43-af143a3a77a4'	System	12 Sep 2020 02:26:27
User entered 'None (0)'	System	12 Sep 2020 02:26:27

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-11T22:23:40', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'a7f42848-7a6d-47c1-ba43-af143a3a77a4'	System	12 Sep 2020 02:26:27
User entered 'None (0)'	System	12 Sep 2020 02:26:27

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-11T22:23:45', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'a7f42848-7a6d-47c1-ba43-af143a3a77a4'	System	12 Sep 2020 02:26:27
User entered 'No (N)'	System	12 Sep 2020 02:26:27

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-11T22:24:04', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'a7f42848-7a6d-47c1-ba43-af143a3a77a4'	System	12 Sep 2020 02:26:27
User entered '11 Sep 2020 22:24'	System	12 Sep 2020 02:26:27

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	09 Sep 2020 19:35:08
User entered 'Day 4'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-12T22:20:49', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '817ea0ce-ab6a-43e6-91e9-55b3b6fba5c0' User entered 'None (0)'	System	13 Sep 2020 02:21:41
	System	13 Sep 2020 02:21:41

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-12T22:20:53', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '817ea0ce-ab6a-43e6-91e9-55b3b6fba5c0' User entered 'None (0)'	System	13 Sep 2020 02:21:41
	System	13 Sep 2020 02:21:41

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-12T22:20:58', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '817ea0ce-ab6a-43e6-91e9-55b3b6fba5c0' User entered 'None (0)'	System	13 Sep 2020 02:21:41
	System	13 Sep 2020 02:21:41

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-12T22:21:02', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '817ea0ce-ab6a-43e6-91e9-55b3b6fba5c0' User entered 'None (0)'	System	13 Sep 2020 02:21:41
	System	13 Sep 2020 02:21:41

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-12T22:21:07', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '817ea0ce-ab6a-43e6-91e9-55b3b6fba5c0' User entered 'None (0)'	System	13 Sep 2020 02:21:41
	System	13 Sep 2020 02:21:41

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-12T22:21:11', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '817ea0ce-ab6a-43e6-91e9-55b3b6fba5c0' User entered 'None (0)'	System	13 Sep 2020 02:21:41
	System	13 Sep 2020 02:21:41

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-12T22:21:23', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '817ea0ce-ab6a-43e6-91e9-55b3b6fba5c0' User entered 'No (N)'	System	13 Sep 2020 02:21:41
	System	13 Sep 2020 02:21:41

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-12T22:21:37', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '817ea0ce-ab6a-43e6-91e9-55b3b6fba5c0'	System	13 Sep 2020 02:21:41
User entered '12 Sep 2020 22:21'	System	13 Sep 2020 02:21:41

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	09 Sep 2020 19:35:08
User entered 'Day 5'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-13T22:35:33', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '298d0fca-3da3-4b58-aa52-34928dae9bbe' User entered 'None (0)'	System	14 Sep 2020 02:36:17
	System	14 Sep 2020 02:36:17

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-13T22:35:38', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '298d0fca-3da3-4b58-aa52-34928dae9bbe' User entered 'None (0)'	System	14 Sep 2020 02:36:17
	System	14 Sep 2020 02:36:17

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-13T22:35:43', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '298d0fca-3da3-4b58-aa52-34928dae9bbe' User entered 'None (0)'	System	14 Sep 2020 02:36:17
	System	14 Sep 2020 02:36:17

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-13T22:35:49', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '298d0fca-3da3-4b58-aa52-34928dae9bbe' User entered 'None (0)'	System	14 Sep 2020 02:36:17
	System	14 Sep 2020 02:36:17

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-13T22:35:53', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '298d0fca-3da3-4b58-aa52-34928dae9bbe' User entered 'None (0)'	System	14 Sep 2020 02:36:17
	System	14 Sep 2020 02:36:17

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-13T22:35:58', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '298d0fca-3da3-4b58-aa52-34928dae9bbe' User entered 'None (0)'	System	14 Sep 2020 02:36:17
	System	14 Sep 2020 02:36:17

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-13T22:36:07', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '298d0fca-3da3-4b58-aa52-34928dae9bbe' User entered 'No (N)'	System	14 Sep 2020 02:36:17
	System	14 Sep 2020 02:36:17

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-13T22:36:13', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '298d0fca-3da3-4b58-aa52-34928dae9bbe' User entered '13 Sep 2020 22:36'	System	14 Sep 2020 02:36:17
	System	14 Sep 2020 02:36:17

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	09 Sep 2020 19:35:08
User entered 'Day 6'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-14T21:58:19', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '33846e19-f544-4ef5-9e53-69254d02d71d' User entered 'None (0)'	System	15 Sep 2020 01:59:06
	System	15 Sep 2020 01:59:06

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-14T21:58:27', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '33846e19-f544-4ef5-9e53-69254d02d71d' User entered 'None (0)'	System	15 Sep 2020 01:59:06
	System	15 Sep 2020 01:59:06

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-14T21:58:34', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '33846e19-f544-4ef5-9e53-69254d02d71d' User entered 'None (0)'	System	15 Sep 2020 01:59:06
	System	15 Sep 2020 01:59:06

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-14T21:58:40', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '33846e19-f544-4ef5-9e53-69254d02d71d' User entered 'None (0)'	System	15 Sep 2020 01:59:06
	System	15 Sep 2020 01:59:06

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-14T21:58:47', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '33846e19-f544-4ef5-9e53-69254d02d71d' User entered 'None (0)'	System	15 Sep 2020 01:59:06
	System	15 Sep 2020 01:59:06

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-14T21:58:51', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '33846e19-f544-4ef5-9e53-69254d02d71d' User entered 'None (0)'	System	15 Sep 2020 01:59:06
	System	15 Sep 2020 01:59:06

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-14T21:58:58', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '33846e19-f544-4ef5-9e53-69254d02d71d' User entered 'No (N)'	System	15 Sep 2020 01:59:06
	System	15 Sep 2020 01:59:06

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-14T21:59:03', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '33846e19-f544-4ef5-9e53-69254d02d71d' User entered '14 Sep 2020 21:59'	System	15 Sep 2020 01:59:06
	System	15 Sep 2020 01:59:06

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	09 Sep 2020 19:35:08
User entered 'Day 7'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-15T21:57:19', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '3a45078b-cdf7-409a-b735-d82741247568' User entered 'None (0)'	System	16 Sep 2020 01:58:10
	System	16 Sep 2020 01:58:10

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-15T21:57:25', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '3a45078b-cdf7-409a-b735-d82741247568' User entered 'None (0)'	System	16 Sep 2020 01:58:10
	System	16 Sep 2020 01:58:10

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-15T21:57:33', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '3a45078b-cdf7-409a-b735-d82741247568' User entered 'None (0)'	System	16 Sep 2020 01:58:10
	System	16 Sep 2020 01:58:10

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-15T21:57:39', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '3a45078b-cdf7-409a-b735-d82741247568' User entered 'None (0)'	System	16 Sep 2020 01:58:10
	System	16 Sep 2020 01:58:10

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-15T21:57:44', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '3a45078b-cdf7-409a-b735-d82741247568' User entered 'None (0)'	System	16 Sep 2020 01:58:10
	System	16 Sep 2020 01:58:10

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-15T21:57:49', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '3a45078b-cdf7-409a-b735-d82741247568' User entered 'None (0)'	System	16 Sep 2020 01:58:10
	System	16 Sep 2020 01:58:10

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-15T21:57:56', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '3a45078b-cdf7-409a-b735-d82741247568' User entered 'No (N)'	System	16 Sep 2020 01:58:10
	System	16 Sep 2020 01:58:10

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-09-15T21:58:09', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '3a45078b-cdf7-409a-b735-d82741247568' User entered '15 Sep 2020 21:58'	System	16 Sep 2020 01:58:10
	System	16 Sep 2020 01:58:10

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 19:35:08

US3632064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 19:35:08

US3632064

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:40:06
User entered 'Yes (Y)'	Catherine Abrams (b) (4)	16 Sep 2020 18:58:36
	(b) (4)	

US3632064

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:40:06
User entered '16 Sep 2020'	Catherine Abrams (b) (4)	16 Sep 2020 18:58:36
	(b) (4)	

US3632064

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:40:06
User entered 'Contact Made (CONTACT MADE)'	Catherine Abrams (b) (4) (b) (4)	16 Sep 2020 18:58:36

US3632064

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:40:06
User entered empty.	Catherine Abrams (b) (4) (b) (4)	16 Sep 2020 18:58:36

US3632064

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:40:14
User entered 'Yes (Y)'	Catherine Abrams (b) (4)	16 Sep 2020 18:58:40
	(b) (4)	

US3632064

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered '1'	System	16 Sep 2020 18:58:40

US3632064

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:40:30
User entered 'Yes (Y)'	Catherine Abrams (b) (4)	24 Sep 2020 13:56:23
	(b) (4)	

US3632064

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:40:30
User entered '24 Sep 2020'	Catherine Abrams (b) (4) (b) (4)	24 Sep 2020 13:56:23

US3632064

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:40:30
User entered 'Contact Made (CONTACT MADE)'	Catherine Abrams (b) (4) (b) (4)	24 Sep 2020 13:56:23

US3632064

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:40:30
User entered empty.	Catherine Abrams (b) (4) (b) (4)	24 Sep 2020 13:56:23

US3632064

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:40:40
User entered 'Yes (Y)'	Catherine Abrams (b) (4)	24 Sep 2020 13:56:29
	(b) (4)	

US3632064

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered '1'	System	24 Sep 2020 13:56:29

US3632064

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:41:15
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4) (b) (4)	30 Sep 2020 16:01:01

US3632064

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:41:15
User entered '30 Sep 2020'	Sarah Wiatrek (b) (4) (b) (4)	30 Sep 2020 16:01:01

US3632064

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:41:15
User entered 'Contact Made (CONTACT MADE)'	Sarah Wiatrek (b) (4) (b) (4)	30 Sep 2020 16:01:01

US3632064

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:41:15
User entered empty.	Sarah Wiatrek (b) (4) (b) (4)	30 Sep 2020 16:01:01

US3632064

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:41:27
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4) (b) (4)	30 Sep 2020 16:01:11

US3632064

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered '1'	System	30 Sep 2020 16:01:11

US3632064

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:41:48
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:29:03

US3632064

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:41:48
User entered '7 Oct 2020'	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:29:03

US3632064

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:41:48
User entered 'Clinic (Clinic)'	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:29:03

US3632064

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered 'VISIT2'	System	07 Oct 2020 18:29:03

US3632064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User accepted default value 'Pre-Dose (PREDOSE)'	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:30:20

US3632064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:43:17
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:30:20

US3632064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:43:17
User entered '7 Oct 2020'	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:30:20

US3632064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:43:17
User entered '12:10'	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:30:20

US3632064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered '7 Oct 2020 12:10'	System	07 Oct 2020 18:30:20

US3632064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:43:17
User entered '98.1' F	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:30:20

US3632064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:43:17
User entered 'Oral (Oral)'	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:30:20

US3632064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:43:17
User entered empty.	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:30:20

US3632064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:43:17
User entered '85'	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:30:20

US3632064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered 'bpm'	System	07 Oct 2020 18:30:20

US3632064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:43:17
User entered '12'	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:30:20

US3632064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered 'breaths/min'	System	07 Oct 2020 18:30:20

US3632064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:43:17
User entered '134'	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:30:20

US3632064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered 'mmHg'	System	07 Oct 2020 18:30:20

US3632064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:43:17
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	08 Oct 2020 06:34:32
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:56:52
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		07 Oct 2020 18:30:20
User entered '59'	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:30:20

US3632064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered 'mmHg'	System	07 Oct 2020 18:30:20

US3632064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User accepted default value 'Post-Dose (POSTDOSE)'	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:30:20

US3632064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:43:17
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:56:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:56:27
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:56:27
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:30:20
User entered empty.	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:30:20

US3632064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:39

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:43:17
User entered '7 Oct 2020' reason for change: Data Entry Error	Kelly Likos (b) (4)	07 Oct 2020 18:56:27
User entered empty.	(b) (4) Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:30:20

US3632064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:43:17
User entered '14:44' reason for change: Data Entry Error	Kelly Likos (b) (4)	07 Oct 2020 18:56:27
User entered empty.	(b) (4) Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:30:20

US3632064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered '7 Oct 2020 14:44'	System	07 Oct 2020 18:56:27
User entered empty.	System	07 Oct 2020 18:30:20

US3632064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:43:17
User entered '97.8' F reason for change: Data Entry Error	Kelly Likos (b) (4)	07 Oct 2020 18:56:27
User entered empty.	(b) (4) Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:30:20

US3632064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:43:17
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 18:56:32
Query 'Data is required. Please provide.' answered by System data change (Site from System).		07 Oct 2020 18:56:32
User entered 'Oral (Oral)' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:56:32
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 18:56:27
User entered empty.	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:30:20

US3632064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:43:17
User entered empty.	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:30:20

US3632064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:43:17
User entered '51' reason for change: Data Entry Error	Kelly Likos (b) (4)	07 Oct 2020 18:56:27
User entered empty.	(b) (4) Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:30:20

US3632064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered 'bpm'	System	07 Oct 2020 18:56:27
User entered empty.	System	07 Oct 2020 18:30:20

US3632064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:43:17
User entered '12' reason for change: Data Entry Error	Kelly Likos (b) (4)	07 Oct 2020 18:56:27
User entered empty.	(b) (4) Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:30:20

US3632064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered 'breaths/min'	System	07 Oct 2020 18:56:27
User entered empty.	System	07 Oct 2020 18:30:20

US3632064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:43:17
User entered '138' reason for change: Data Entry Error	Kelly Likos (b) (4)	07 Oct 2020 18:56:27
User entered empty.	(b) (4) Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:30:20

US3632064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered 'mmHg'	System	07 Oct 2020 18:56:27
User entered empty.	System	07 Oct 2020 18:30:20

US3632064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:43:17
User entered '70' reason for change: Data Entry Error	Kelly Likos (b) (4)	07 Oct 2020 18:56:27
User entered empty.	(b) (4) Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:30:20

US3632064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered 'mmHg'	System	07 Oct 2020 18:56:27
User entered empty.	System	07 Oct 2020 18:30:20

US3632064

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:14:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:43:24
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:30:52

US3632064

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:14:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:43:24
User entered '7 Oct 2020'	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:30:52

US3632064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:43:59
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:27:49

US3632064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:39

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:43:59
User entered empty.	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:27:49

US3632064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:43:59
User entered empty.	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:27:49

US3632064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered 'MRNA-1273 OR PLACEBO'	System	07 Oct 2020 18:27:49

US3632064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:43:59
User entered '7 Oct 2020'	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:27:49

US3632064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:43:59
User entered '14:14'	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:27:49

US3632064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered '7 Oct 2020 14:14'	System	07 Oct 2020 18:27:49

US3632064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:43:59
User entered 'Left Arm (LEFT ARM)'	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:27:49

US3632064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:43:59
User entered 'ONCE'	System	07 Oct 2020 18:27:49

US3632064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:39

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered 'INTRAMUSCULAR'	System	07 Oct 2020 18:27:49

US3632064

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:44:21
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:31:43

US3632064

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:44:21
User entered '7 Oct 2020'	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:31:43

US3632064

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:44:21
User entered '12:50'	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:31:43

US3632064

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered '7 Oct 2020 12:50'	System	07 Oct 2020 18:31:43

US3632064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:14:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:44:30
User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	07 Oct 2020 18:34:18
Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System).	System	07 Oct 2020 18:34:18
User entered '7 Oct 2020' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:34:18
User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	07 Oct 2020 18:33:54
User entered empty.	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:33:54

US3632064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:14:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:33:54

US3632064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:14:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:44:30
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:33:54

US3632064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:14:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:44:30
User entered '12:52'	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:33:54

US3632064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered '7 Oct 2020 12:52'	System	07 Oct 2020 18:34:18
User entered empty.	System	07 Oct 2020 18:33:54

US3632064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:14:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:33:54

US3632064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:14:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:44:30
User entered 'No (N)'	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:33:54

US3632064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:14:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:44:30
User entered empty.	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:33:54

US3632064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered empty.	System	07 Oct 2020 18:33:54

US3632064

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:44:43
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	07 Oct 2020 18:35:06

US3632064

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered '1'	System	07 Oct 2020 18:35:06

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	07 Oct 2020 18:27:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-07T14:48:13', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '37f79602-dcf1-47b8-b335-b9bb8543b141' User entered 'Yes (Y)'	System	07 Oct 2020 18:48:56
	System	07 Oct 2020 18:48:56

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-07T14:48:32', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '37f79602-dcf1-47b8-b335-b9bb8543b141' User entered '97.8'	System	07 Oct 2020 18:48:56
	System	07 Oct 2020 18:48:56

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-07T14:48:39', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '37f79602-dcf1-47b8-b335-b9bb8543b141'	System	07 Oct 2020 18:48:56
User entered 'No (N)'	System	07 Oct 2020 18:48:56

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-07T14:48:50', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '37f79602-dcf1-47b8-b335-b9bb8543b141' User entered '07 Oct 2020 14:48'	System	07 Oct 2020 18:48:56
	System	07 Oct 2020 18:48:56

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '07 Oct 2020 14:34'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '07 Oct 2020 17:04'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	07 Oct 2020 18:27:49
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-07T23:10:09', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '0c2aab51-e13e-4962-ba8d-0b4e15fbf377' User entered 'Yes (Y)'	System	08 Oct 2020 03:10:40
	System	08 Oct 2020 03:10:40

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-07T23:10:18', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '0c2aab51-e13e-4962-ba8d-0b4e15fbf377' User entered '97.5'	System	08 Oct 2020 03:10:40
	System	08 Oct 2020 03:10:40

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-07T23:10:24', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '0c2aab51-e13e-4962-ba8d-0b4e15fbf377'	System	08 Oct 2020 03:10:40
User entered 'No (N)'	System	08 Oct 2020 03:10:40

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-07T23:10:35', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '0c2aab51-e13e-4962-ba8d-0b4e15fbf377' User entered '07 Oct 2020 23:10'	System	08 Oct 2020 03:10:40
	System	08 Oct 2020 03:10:40

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '07 Oct 2020 17:59'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	07 Oct 2020 18:27:49
User entered 'Day 2'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-08T22:34:44', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '68679fee-a92e-4d08-8144-354141f0f8ad' User entered 'Yes (Y)'	System	09 Oct 2020 02:35:22
	System	09 Oct 2020 02:35:22

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-08T22:34:56', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '68679fee-a92e-4d08-8144-354141f0f8ad' User entered '97.8'	System	09 Oct 2020 02:35:22
	System	09 Oct 2020 02:35:22

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-08T22:35:08', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '68679fee-a92e-4d08-8144-354141f0f8ad'	System	09 Oct 2020 02:35:22
User entered 'No (N)'	System	09 Oct 2020 02:35:22

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-08T22:35:18', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '68679fee-a92e-4d08-8144-354141f0f8ad' User entered '08 Oct 2020 22:35'	System	09 Oct 2020 02:35:22
	System	09 Oct 2020 02:35:22

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	07 Oct 2020 18:27:49
User entered 'Day 3'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-09T22:55:30', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '6135dfe5-07ff-43cc-a8a3-c2852b64d6b6' User entered 'Yes (Y)'	System	10 Oct 2020 02:56:36
	System	10 Oct 2020 02:56:36

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-09T22:55:51', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '6135dfe5-07ff-43cc-a8a3-c2852b64d6b6' User entered '97.4'	System	10 Oct 2020 02:56:36
	System	10 Oct 2020 02:56:36

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-09T22:55:59', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '6135dfe5-07ff-43cc-a8a3-c2852b64d6b6'	System	10 Oct 2020 02:56:36
User entered 'No (N)'	System	10 Oct 2020 02:56:36

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-09T22:56:29', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '6135dfe5-07ff-43cc-a8a3-c2852b64d6b6' User entered '09 Oct 2020 22:56'	System	10 Oct 2020 02:56:36
	System	10 Oct 2020 02:56:36

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	07 Oct 2020 18:27:49
User entered 'Day 4'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-10T23:00:05', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '2264b822-6aad-4400-a480-3908b4a6a7d4' User entered 'Yes (Y)'	System	11 Oct 2020 03:00:38
	System	11 Oct 2020 03:00:38

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-10T23:00:15', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '2264b822-6aad-4400-a480-3908b4a6a7d4' User entered '98.1'	System	11 Oct 2020 03:00:38
	System	11 Oct 2020 03:00:38

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-10T23:00:21', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '2264b822-6aad-4400-a480-3908b4a6a7d4'	System	11 Oct 2020 03:00:38
User entered 'No (N)'	System	11 Oct 2020 03:00:38

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-10T23:00:33', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '2264b822-6aad-4400-a480-3908b4a6a7d4' User entered '10 Oct 2020 23:00'	System	11 Oct 2020 03:00:38
	System	11 Oct 2020 03:00:38

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	07 Oct 2020 18:27:49
User entered 'Day 5'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-11T22:38:06', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'f3a7c9cc-14b5-4f5d-87bc-3ba9a4386210' User entered 'Yes (Y)'	System	12 Oct 2020 02:38:37
	System	12 Oct 2020 02:38:37

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-11T22:38:16', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'f3a7c9cc-14b5-4f5d-87bc-3ba9a4386210' User entered '98.4'	System	12 Oct 2020 02:38:37
	System	12 Oct 2020 02:38:37

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-11T22:38:21', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'f3a7c9cc-14b5-4f5d-87bc-3ba9a4386210'	System	12 Oct 2020 02:38:37
User entered 'No (N)'	System	12 Oct 2020 02:38:37

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-11T22:38:31', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'f3a7c9cc-14b5-4f5d-87bc-3ba9a4386210' User entered '11 Oct 2020 22:38'	System	12 Oct 2020 02:38:37
	System	12 Oct 2020 02:38:37

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	07 Oct 2020 18:27:49
User entered 'Day 6'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-12T22:20:24', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '0a9bdf4d-2084-458b-9b94-cd305ef4ef68' User entered 'Yes (Y)'	System	13 Oct 2020 02:22:00
	System	13 Oct 2020 02:22:00

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-12T22:21:12', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '0a9bdf4d-2084-458b-9b94-cd305ef4ef68' User entered '97.6'	System	13 Oct 2020 02:22:00
	System	13 Oct 2020 02:22:00

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-12T22:21:20', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '0a9bdffd-2084-458b-9b94-cd305ef4ef68' User entered 'No (N)'	System	13 Oct 2020 02:22:00
	System	13 Oct 2020 02:22:00

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-12T22:21:58', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '0a9bdffd-2084-458b-9b94-cd305ef4ef68' User entered '12 Oct 2020 22:21'	System	13 Oct 2020 02:22:00
	System	13 Oct 2020 02:22:00

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	07 Oct 2020 18:27:49
User entered 'Day 7'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-13T22:44:17', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'f135cb6d-215d-4ff0-89f7-6cfaa617c01d' User entered 'Yes (Y)'	System	14 Oct 2020 02:45:08
	System	14 Oct 2020 02:45:08

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-13T22:44:42', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'f135cb6d-215d-4ff0-89f7-6cfaa617c01d' User entered '97.8'	System	14 Oct 2020 02:45:08
	System	14 Oct 2020 02:45:08

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-13T22:44:51', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'f135cb6d-215d-4ff0-89f7-6cfaa617c01d'	System	14 Oct 2020 02:45:08
User entered 'No (N)'	System	14 Oct 2020 02:45:08

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-13T22:45:02', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'f135cb6d-215d-4ff0-89f7-6cfaa617c01d' User entered '13 Oct 2020 22:45'	System	14 Oct 2020 02:45:08
	System	14 Oct 2020 02:45:08

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	07 Oct 2020 18:27:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-07T14:49:01', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'a7b5160a-1f1a-4748-9fe1-c2fae59808b5'	System	07 Oct 2020 18:49:34
User entered 'None (1)'	System	07 Oct 2020 18:49:34

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-07T14:49:07', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'a7b5160a-1f1a-4748-9fe1-c2fae59808b5'	System	07 Oct 2020 18:49:34
User entered 'No (N)'	System	07 Oct 2020 18:49:34

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-07T14:49:12', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'a7b5160a-1f1a-4748-9fe1-c2fae59808b5'	System	07 Oct 2020 18:49:34
User entered 'No (N)'	System	07 Oct 2020 18:49:34

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-07T14:49:19', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'a7b5160a-1f1a-4748-9fe1-c2fae59808b5'	System	07 Oct 2020 18:49:34
User entered 'None (1)'	System	07 Oct 2020 18:49:34

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-07T14:49:29', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'a7b5160a-1f1a-4748-9fe1-c2fae59808b5' User entered '07 Oct 2020 14:49'	System	07 Oct 2020 18:49:34
	System	07 Oct 2020 18:49:34

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '07 Oct 2020 14:34'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '07 Oct 2020 17:04'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	07 Oct 2020 18:27:49
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-07T23:10:47', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '6477279c-81c1-434c-a999-bdd7d48e6464'	System	08 Oct 2020 03:11:24
User entered 'None (1)'	System	08 Oct 2020 03:11:24

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-07T23:10:52', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '6477279c-81c1-434c-a999-bdd7d48e6464' User entered 'No (N)'	System	08 Oct 2020 03:11:24
	System	08 Oct 2020 03:11:24

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-07T23:10:59', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '6477279c-81c1-434c-a999-bdd7d48e6464' User entered 'No (N)'	System	08 Oct 2020 03:11:24
	System	08 Oct 2020 03:11:24

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-07T23:11:06', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '6477279c-81c1-434c-a999-bdd7d48e6464'	System	08 Oct 2020 03:11:24
User entered 'None (1)'	System	08 Oct 2020 03:11:24

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-07T23:11:21', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '6477279c-81c1-434c-a999-bdd7d48e6464' User entered '07 Oct 2020 23:11'	System	08 Oct 2020 03:11:24
	System	08 Oct 2020 03:11:24

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '07 Oct 2020 17:59'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	07 Oct 2020 18:27:49
User entered 'Day 2'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-08T22:35:32', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'a8517686-d221-4d52-b811-841611dbe785'	System	09 Oct 2020 02:37:12
User entered 'Does not interfere with activity (2)'	System	09 Oct 2020 02:37:12

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-08T22:35:39', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'a8517686-d221-4d52-b811-841611dbe785'	System	09 Oct 2020 02:37:12
User entered 'No (N)'	System	09 Oct 2020 02:37:12

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-08T22:35:46', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'a8517686-d221-4d52-b811-841611dbe785' User entered 'Yes (Y)'	System	09 Oct 2020 02:37:12
	System	09 Oct 2020 02:37:12

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:39

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-08T22:36:29', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'a8517686-d221-4d52-b811-841611dbe785'	System	09 Oct 2020 02:37:12
User entered '2'	System	09 Oct 2020 02:37:12

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-08T22:36:38', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'a8517686-d221-4d52-b811-841611dbe785'	System	09 Oct 2020 02:37:12
User entered 'None (1)'	System	09 Oct 2020 02:37:12

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-08T22:37:10', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'a8517686-d221-4d52-b811-841611dbe785' User entered '08 Oct 2020 22:37'	System	09 Oct 2020 02:37:12
	System	09 Oct 2020 02:37:12

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	07 Oct 2020 18:27:49
User entered 'Day 3'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-09T22:57:04', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '14a137f8-2476-4368-b33b-218afd6e27ee'	System	10 Oct 2020 03:00:55
User entered 'Does not interfere with activity (2)'	System	10 Oct 2020 03:00:55

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-09T22:57:12', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '14a137f8-2476-4368-b33b-218afd6e27ee' User entered 'Yes (Y)'	System	10 Oct 2020 03:00:55
	System	10 Oct 2020 03:00:55

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:39

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-09T23:00:19', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '14a137f8-2476-4368-b33b-218afd6e27ee' User entered '50'	System	10 Oct 2020 03:00:55
	System	10 Oct 2020 03:00:55

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-09T22:59:09', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '14a137f8-2476-4368-b33b-218afd6e27ee' User entered 'No (N)'	System	10 Oct 2020 03:00:55
	System	10 Oct 2020 03:00:55

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-09T22:59:17', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '14a137f8-2476-4368-b33b-218afd6e27ee'	System	10 Oct 2020 03:00:55
User entered 'None (1)'	System	10 Oct 2020 03:00:55

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-09T23:00:50', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '14a137f8-2476-4368-b33b-218afd6e27ee' User entered '09 Oct 2020 23:00'	System	10 Oct 2020 03:00:55
	System	10 Oct 2020 03:00:55

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	07 Oct 2020 18:27:49
User entered 'Day 4'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-10T23:00:48', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '63361d9d-98b5-402a-9ff0-f00fe8842648'	System	11 Oct 2020 03:01:19
User entered 'None (1)'	System	11 Oct 2020 03:01:19

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-10T23:00:53', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '63361d9d-98b5-402a-9ff0-f00fe8842648'	System	11 Oct 2020 03:01:19
User entered 'No (N)'	System	11 Oct 2020 03:01:19

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-10T23:00:58', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '63361d9d-98b5-402a-9ff0-f00fe8842648'	System	11 Oct 2020 03:01:19
User entered 'No (N)'	System	11 Oct 2020 03:01:19

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-10T23:01:05', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '63361d9d-98b5-402a-9ff0-f00fe8842648'	System	11 Oct 2020 03:01:19
User entered 'None (1)'	System	11 Oct 2020 03:01:19

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-10T23:01:15', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '63361d9d-98b5-402a-9ff0-f00fe8842648' User entered '10 Oct 2020 23:01'	System	11 Oct 2020 03:01:19
	System	11 Oct 2020 03:01:19

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	07 Oct 2020 18:27:49
User entered 'Day 5'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-11T22:38:41', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '717f7f90-f525-4d1f-9ec2-7330ce6f25af'	System	12 Oct 2020 02:39:20
User entered 'None (1)'	System	12 Oct 2020 02:39:20

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-11T22:38:46', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '717f7f90-f525-4d1f-9ec2-7330ce6f25af' User entered 'No (N)'	System	12 Oct 2020 02:39:20
	System	12 Oct 2020 02:39:20

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-11T22:38:51', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '717f7f90-f525-4d1f-9ec2-7330ce6f25af' User entered 'No (N)'	System	12 Oct 2020 02:39:20
	System	12 Oct 2020 02:39:20

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-11T22:38:57', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '717f7f90-f525-4d1f-9ec2-7330ce6f25af'	System	12 Oct 2020 02:39:20
User entered 'None (1)'	System	12 Oct 2020 02:39:20

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-11T22:39:15', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '717f7f90-f525-4d1f-9ec2-7330ce6f25af' User entered '11 Oct 2020 22:39'	System	12 Oct 2020 02:39:20
	System	12 Oct 2020 02:39:20

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	07 Oct 2020 18:27:49
User entered 'Day 6'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-12T22:22:28', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'd3fe8d57-0b21-491a-8225-207ac52456f5'	System	13 Oct 2020 02:22:54
User entered 'None (1)'	System	13 Oct 2020 02:22:54

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-12T22:22:33', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'd3fe8d57-0b21-491a-8225-207ac52456f5'	System	13 Oct 2020 02:22:54
User entered 'No (N)'	System	13 Oct 2020 02:22:54

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-12T22:22:37', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'd3fe8d57-0b21-491a-8225-207ac52456f5' User entered 'No (N)'	System	13 Oct 2020 02:22:54
	System	13 Oct 2020 02:22:54

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-12T22:22:43', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'd3fe8d57-0b21-491a-8225-207ac52456f5'	System	13 Oct 2020 02:22:54
User entered 'None (1)'	System	13 Oct 2020 02:22:54

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-12T22:22:52', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'd3fe8d57-0b21-491a-8225-207ac52456f5' User entered '12 Oct 2020 22:22'	System	13 Oct 2020 02:22:54
	System	13 Oct 2020 02:22:54

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	07 Oct 2020 18:27:49
User entered 'Day 7'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-13T22:45:12', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'cf0ce079-78e2-4c4e-acfd-3813c582a26f'	System	14 Oct 2020 02:45:45
User entered 'None (1)'	System	14 Oct 2020 02:45:45

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-13T22:45:17', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'cf0ce079-78e2-4c4e-acfd-3813c582a26f' User entered 'No (N)'	System	14 Oct 2020 02:45:45
	System	14 Oct 2020 02:45:45

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-13T22:45:22', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'cf0ce079-78e2-4c4e-acfd-3813c582a26f' User entered 'No (N)'	System	14 Oct 2020 02:45:45
	System	14 Oct 2020 02:45:45

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-13T22:45:29', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'cf0ce079-78e2-4c4e-acfd-3813c582a26f'	System	14 Oct 2020 02:45:45
User entered 'None (1)'	System	14 Oct 2020 02:45:45

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-13T22:45:42', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'cf0ce079-78e2-4c4e-acfd-3813c582a26f' User entered '13 Oct 2020 22:45'	System	14 Oct 2020 02:45:45
	System	14 Oct 2020 02:45:45

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	07 Oct 2020 18:27:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-07T14:49:40', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '171e74ff-f95b-4be0-8b17-a794c5024a27'	System	07 Oct 2020 18:50:25
User entered 'None (0)'	System	07 Oct 2020 18:50:25

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-07T14:49:44', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '171e74ff-f95b-4be0-8b17-a794c5024a27'	System	07 Oct 2020 18:50:25
User entered 'None (0)'	System	07 Oct 2020 18:50:25

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-07T14:49:49', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '171e74ff-f95b-4be0-8b17-a794c5024a27'	System	07 Oct 2020 18:50:25
User entered 'None (0)'	System	07 Oct 2020 18:50:25

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-07T14:49:53', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '171e74ff-f95b-4be0-8b17-a794c5024a27'	System	07 Oct 2020 18:50:25
User entered 'None (0)'	System	07 Oct 2020 18:50:25

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-07T14:49:56', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '171e74ff-f95b-4be0-8b17-a794c5024a27'	System	07 Oct 2020 18:50:25
User entered 'None (0)'	System	07 Oct 2020 18:50:25

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-07T14:50:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '171e74ff-f95b-4be0-8b17-a794c5024a27'	System	07 Oct 2020 18:50:25
User entered 'None (0)'	System	07 Oct 2020 18:50:25

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-07T14:50:06', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '171e74ff-f95b-4be0-8b17-a794c5024a27'	System	07 Oct 2020 18:50:25
User entered 'No (N)'	System	07 Oct 2020 18:50:25

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-07T14:50:21', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '171e74ff-f95b-4be0-8b17-a794c5024a27' User entered '07 Oct 2020 14:50'	System	07 Oct 2020 18:50:25
	System	07 Oct 2020 18:50:25

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '07 Oct 2020 14:34'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '07 Oct 2020 17:04'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	07 Oct 2020 18:27:49
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-07T23:11:31', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '04e067eb-4442-4c2f-b9e2-8d6f66de44c5' User entered 'None (0)'	System	08 Oct 2020 03:12:32
	System	08 Oct 2020 03:12:32

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-07T23:11:36', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '04e067eb-4442-4c2f-b9e2-8d6f66de44c5' User entered 'None (0)'	System	08 Oct 2020 03:12:32
	System	08 Oct 2020 03:12:32

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-07T23:11:50', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '04e067eb-4442-4c2f-b9e2-8d6f66de44c5' User entered 'None (0)'	System	08 Oct 2020 03:12:32
	System	08 Oct 2020 03:12:32

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-07T23:11:59', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '04e067eb-4442-4c2f-b9e2-8d6f66de44c5' User entered 'None (0)'	System	08 Oct 2020 03:12:32
	System	08 Oct 2020 03:12:32

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-07T23:12:03', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '04e067eb-4442-4c2f-b9e2-8d6f66de44c5' User entered 'None (0)'	System	08 Oct 2020 03:12:32
	System	08 Oct 2020 03:12:32

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-07T23:12:07', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '04e067eb-4442-4c2f-b9e2-8d6f66de44c5' User entered 'None (0)'	System	08 Oct 2020 03:12:32
	System	08 Oct 2020 03:12:32

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-07T23:12:14', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '04e067eb-4442-4c2f-b9e2-8d6f66de44c5' User entered 'No (N)'	System	08 Oct 2020 03:12:32
	System	08 Oct 2020 03:12:32

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-07T23:12:29', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '04e067eb-4442-4c2f-b9e2-8d6f66de44c5' User entered '07 Oct 2020 23:12'	System	08 Oct 2020 03:12:32
	System	08 Oct 2020 03:12:32

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '07 Oct 2020 17:59'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	07 Oct 2020 18:27:49
User entered 'Day 2'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-08T22:37:18', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'ba9d804e-fcb9-4b34-89c1-5e054782a790' User entered 'None (0)'	System	09 Oct 2020 02:38:18
	System	09 Oct 2020 02:38:18

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-08T22:37:24', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'ba9d804e-fcb9-4b34-89c1-5e054782a790' User entered 'None (0)'	System	09 Oct 2020 02:38:18
	System	09 Oct 2020 02:38:18

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-08T22:37:28', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'ba9d804e-fcb9-4b34-89c1-5e054782a790'	System	09 Oct 2020 02:38:18
User entered 'None (0)'	System	09 Oct 2020 02:38:18

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-08T22:37:38', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'ba9d804e-fcb9-4b34-89c1-5e054782a790' User entered 'None (0)'	System	09 Oct 2020 02:38:18
	System	09 Oct 2020 02:38:18

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-08T22:37:42', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'ba9d804e-fcb9-4b34-89c1-5e054782a790'	System	09 Oct 2020 02:38:18
User entered 'None (0)'	System	09 Oct 2020 02:38:18

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-08T22:37:46', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'ba9d804e-fcb9-4b34-89c1-5e054782a790' User entered 'None (0)'	System	09 Oct 2020 02:38:18
	System	09 Oct 2020 02:38:18

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-08T22:37:54', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'ba9d804e-fcb9-4b34-89c1-5e054782a790' User entered 'No (N)'	System	09 Oct 2020 02:38:18
	System	09 Oct 2020 02:38:18

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-08T22:38:14', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'ba9d804e-fcb9-4b34-89c1-5e054782a790'	System	09 Oct 2020 02:38:18
User entered '08 Oct 2020 22:38'	System	09 Oct 2020 02:38:18

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	07 Oct 2020 18:27:49
User entered 'Day 3'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-09T23:01:12', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '1442d994-b3ce-4efe-a061-51baba5e16f0' User entered 'None (0)'	System	10 Oct 2020 03:02:34
	System	10 Oct 2020 03:02:34

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-09T23:01:17', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '1442d994-b3ce-4efe-a061-51baba5e16f0' User entered 'None (0)'	System	10 Oct 2020 03:02:34
	System	10 Oct 2020 03:02:34

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-09T23:01:24', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '1442d994-b3ce-4efe-a061-51baba5e16f0' User entered 'None (0)'	System	10 Oct 2020 03:02:34
	System	10 Oct 2020 03:02:34

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-09T23:01:30', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '1442d994-b3ce-4efe-a061-51baba5e16f0' User entered 'None (0)'	System	10 Oct 2020 03:02:34
	System	10 Oct 2020 03:02:34

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-09T23:01:35', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '1442d994-b3ce-4efe-a061-51baba5e16f0' User entered 'None (0)'	System	10 Oct 2020 03:02:34
	System	10 Oct 2020 03:02:34

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-09T23:01:40', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '1442d994-b3ce-4efe-a061-51baba5e16f0' User entered 'None (0)'	System	10 Oct 2020 03:02:34
	System	10 Oct 2020 03:02:34

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-09T23:01:45', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '1442d994-b3ce-4efe-a061-51baba5e16f0' User entered 'No (N)'	System	10 Oct 2020 03:02:34
	System	10 Oct 2020 03:02:34

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-09T23:02:27', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '1442d994-b3ce-4efe-a061-51baba5e16f0' User entered '09 Oct 2020 23:02'	System	10 Oct 2020 03:02:34
	System	10 Oct 2020 03:02:34

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	07 Oct 2020 18:27:49
User entered 'Day 4'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-10T23:01:23', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'f70ec847-c059-4a98-a490-e4092e05b8b9' User entered 'None (0)'	System	11 Oct 2020 03:02:11
	System	11 Oct 2020 03:02:11

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-10T23:01:27', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'f70ec847-c059-4a98-a490-e4092e05b8b9' User entered 'None (0)'	System	11 Oct 2020 03:02:11
	System	11 Oct 2020 03:02:11

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-10T23:01:33', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'f70ec847-c059-4a98-a490-e4092e05b8b9' User entered 'None (0)'	System	11 Oct 2020 03:02:11
	System	11 Oct 2020 03:02:11

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-10T23:01:38', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'f70ec847-c059-4a98-a490-e4092e05b8b9' User entered 'None (0)'	System	11 Oct 2020 03:02:11
	System	11 Oct 2020 03:02:11

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-10T23:01:42', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'f70ec847-c059-4a98-a490-e4092e05b8b9' User entered 'None (0)'	System	11 Oct 2020 03:02:11
	System	11 Oct 2020 03:02:11

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-10T23:01:46', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'f70ec847-c059-4a98-a490-e4092e05b8b9' User entered 'None (0)'	System	11 Oct 2020 03:02:11
	System	11 Oct 2020 03:02:11

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-10T23:01:52', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'f70ec847-c059-4a98-a490-e4092e05b8b9' User entered 'No (N)'	System	11 Oct 2020 03:02:11
	System	11 Oct 2020 03:02:11

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-10T23:02:06', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'f70ec847-c059-4a98-a490-e4092e05b8b9' User entered '10 Oct 2020 23:02'	System	11 Oct 2020 03:02:11
	System	11 Oct 2020 03:02:11

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	07 Oct 2020 18:27:49
User entered 'Day 5'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-11T22:39:24', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '5f091223-24b8-4ef6-9517-8c9185fbc63e' User entered 'None (0)'	System	12 Oct 2020 02:40:17
	System	12 Oct 2020 02:40:17

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-11T22:39:30', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '5f091223-24b8-4ef6-9517-8c9185fbc63e' User entered 'None (0)'	System	12 Oct 2020 02:40:17
	System	12 Oct 2020 02:40:17

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-11T22:39:35', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '5f091223-24b8-4ef6-9517-8c9185fbc63e' User entered 'None (0)'	System	12 Oct 2020 02:40:17
	System	12 Oct 2020 02:40:17

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-11T22:39:39', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '5f091223-24b8-4ef6-9517-8c9185fbc63e' User entered 'None (0)'	System	12 Oct 2020 02:40:17
	System	12 Oct 2020 02:40:17

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-11T22:39:43', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '5f091223-24b8-4ef6-9517-8c9185fbc63e' User entered 'None (0)'	System	12 Oct 2020 02:40:17
	System	12 Oct 2020 02:40:17

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-11T22:39:47', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '5f091223-24b8-4ef6-9517-8c9185fbc63e' User entered 'None (0)'	System	12 Oct 2020 02:40:17
	System	12 Oct 2020 02:40:17

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-11T22:39:52', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '5f091223-24b8-4ef6-9517-8c9185fbc63e' User entered 'No (N)'	System	12 Oct 2020 02:40:17
	System	12 Oct 2020 02:40:17

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-11T22:40:13', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '5f091223-24b8-4ef6-9517-8c9185fbc63e' User entered '11 Oct 2020 22:40'	System	12 Oct 2020 02:40:17
	System	12 Oct 2020 02:40:17

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	07 Oct 2020 18:27:49
User entered 'Day 6'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-12T22:23:01', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '6d6316d4-d3f2-4932-86de-450746a67c80' User entered 'None (0)'	System	13 Oct 2020 02:23:45
	System	13 Oct 2020 02:23:45

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-12T22:23:06', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '6d6316d4-d3f2-4932-86de-450746a67c80' User entered 'None (0)'	System	13 Oct 2020 02:23:45
	System	13 Oct 2020 02:23:45

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-12T22:23:11', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '6d6316d4-d3f2-4932-86de-450746a67c80' User entered 'None (0)'	System	13 Oct 2020 02:23:45
	System	13 Oct 2020 02:23:45

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-12T22:23:15', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '6d6316d4-d3f2-4932-86de-450746a67c80' User entered 'None (0)'	System	13 Oct 2020 02:23:45
	System	13 Oct 2020 02:23:45

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-12T22:23:19', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '6d6316d4-d3f2-4932-86de-450746a67c80' User entered 'None (0)'	System	13 Oct 2020 02:23:45
	System	13 Oct 2020 02:23:45

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-12T22:23:23', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '6d6316d4-d3f2-4932-86de-450746a67c80' User entered 'None (0)'	System	13 Oct 2020 02:23:45
	System	13 Oct 2020 02:23:45

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-12T22:23:29', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '6d6316d4-d3f2-4932-86de-450746a67c80' User entered 'No (N)'	System	13 Oct 2020 02:23:45
	System	13 Oct 2020 02:23:45

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-12T22:23:43', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '6d6316d4-d3f2-4932-86de-450746a67c80' User entered '12 Oct 2020 22:23'	System	13 Oct 2020 02:23:45
	System	13 Oct 2020 02:23:45

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	07 Oct 2020 18:27:49
User entered 'Day 7'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-13T22:45:55', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '018256d9-9958-4a60-a74e-06a576f90de7' User entered 'None (0)'	System	14 Oct 2020 02:46:44
	System	14 Oct 2020 02:46:44

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-13T22:45:59', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '018256d9-9958-4a60-a74e-06a576f90de7' User entered 'None (0)'	System	14 Oct 2020 02:46:44
	System	14 Oct 2020 02:46:44

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-13T22:46:04', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '018256d9-9958-4a60-a74e-06a576f90de7' User entered 'None (0)'	System	14 Oct 2020 02:46:44
	System	14 Oct 2020 02:46:44

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-13T22:46:08', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '018256d9-9958-4a60-a74e-06a576f90de7' User entered 'None (0)'	System	14 Oct 2020 02:46:44
	System	14 Oct 2020 02:46:44

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-13T22:46:12', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '018256d9-9958-4a60-a74e-06a576f90de7' User entered 'None (0)'	System	14 Oct 2020 02:46:44
	System	14 Oct 2020 02:46:44

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-13T22:46:16', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '018256d9-9958-4a60-a74e-06a576f90de7' User entered 'None (0)'	System	14 Oct 2020 02:46:44
	System	14 Oct 2020 02:46:44

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-13T22:46:22', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '018256d9-9958-4a60-a74e-06a576f90de7' User entered 'No (N)'	System	14 Oct 2020 02:46:44
	System	14 Oct 2020 02:46:44

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-10-13T22:46:39', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '018256d9-9958-4a60-a74e-06a576f90de7' User entered '13 Oct 2020 22:46'	System	14 Oct 2020 02:46:44
	System	14 Oct 2020 02:46:44

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 18:27:49

US3632064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 18:27:49

US3632064

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:45:04
User entered 'Yes (Y)'	Christina Bacher (b) (4) (b) (4)	14 Oct 2020 13:05:40

US3632064

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:45:04
User entered '14 Oct 2020'	Christina Bacher (b) (4) (b) (4)	14 Oct 2020 13:05:40

US3632064

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:45:04
User entered 'Contact Made (CONTACT MADE)'	Christina Bacher (b) (4) (b) (4)	14 Oct 2020 13:05:40

US3632064

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:45:04
User entered empty.	Christina Bacher (b) (4) (b) (4)	14 Oct 2020 13:05:40

US3632064

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:45:18
User entered 'Yes (Y)'	Christina Bacher (b) (4) (b) (4)	14 Oct 2020 13:05:46

US3632064

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered '1'	System	14 Oct 2020 13:05:46

US3632064

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:45:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 15:07:14

US3632064

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:45:26
User entered '21 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 15:07:14

US3632064

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:45:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	21 Oct 2020 15:07:14

US3632064

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:45:26
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 15:07:14

US3632064

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:45:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 15:07:21

US3632064

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered '1'	System	21 Oct 2020 15:07:21

US3632064

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:46:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 16:06:46

US3632064

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:46:29
User entered '28 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 16:06:46

US3632064

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:46:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Oct 2020 16:06:46

US3632064

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:46:29
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 16:06:46

US3632064

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:46:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 16:06:50

US3632064

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered '1'	System	28 Oct 2020 16:06:50

US3632064

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:48:47
User entered 'Yes (Y)'	Bezuayehu Mandefro (b) (4)	04 Nov 2020 18:15:32

US3632064

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:39

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:48:47
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Nov 2020 18:16:07
User entered '04 Nov 2020' reason for change: New Information	Bezuayehu Mandefro (b) (4)	04 Nov 2020 18:16:07
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Nov 2020 18:15:32
User entered ' Nov ' (non-conformant).	Bezuayehu Mandefro (b) (4)	04 Nov 2020 18:15:32

US3632064

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:48:47
User entered 'Clinic (Clinic)'	Bezuayehu Mandefro (b) (4)	04 Nov 2020 18:15:32

US3632064

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered 'VISIT3'	System	04 Nov 2020 18:15:32

US3632064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:49:07
User entered 'No (N)'	Bezuayehu Mandefro (b) (4)	04 Nov 2020 18:16:28

US3632064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:49:07
User entered empty.	Bezuayehu Mandefro (b) (4)	04 Nov 2020 18:16:28

US3632064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:49:07
User entered empty.	Bezuayehu Mandefro (b) (4)	04 Nov 2020 18:16:28

US3632064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered empty.	System	04 Nov 2020 18:16:28

US3632064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:49:07
User entered empty.	Bezuayehu Mandefro (b) (4)	04 Nov 2020 18:16:28

US3632064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:49:07
User entered empty.	Bezuayehu Mandefro (b) (4)	04 Nov 2020 18:16:28

US3632064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:49:07
User entered empty.	Bezuayehu Mandefro (b) (4)	04 Nov 2020 18:16:28

US3632064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:49:07
User entered empty.	Bezuayehu Mandefro (b) (4)	04 Nov 2020 18:16:28

US3632064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered empty.	System	04 Nov 2020 18:16:28

US3632064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:49:07
User entered empty.	Bezuayehu Mandefro (b) (4)	04 Nov 2020 18:16:28

US3632064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered empty.	System	04 Nov 2020 18:16:28

US3632064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:49:07
User entered empty.	Bezuayehu Mandefro (b) (4)	04 Nov 2020 18:16:28

US3632064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered empty.	System	04 Nov 2020 18:16:28

US3632064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:49:07
User entered empty.	Bezuayehu Mandefro (b) (4)	04 Nov 2020 18:16:28

US3632064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered empty.	System	04 Nov 2020 18:16:28

US3632064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56

US3632064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56

US3632064

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:14:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:49:15
User entered 'No (N)'	Bezuayehu Mandefro (b) (4)	04 Nov 2020 18:16:39

US3632064

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:14:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:49:15
User entered empty.	Bezuayehu Mandefro (b) (4)	04 Nov 2020 18:16:39

US3632064

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:49:22
User entered 'Yes (Y)'	Bezuayehu Mandefro (b) (4)	04 Nov 2020 18:17:14

US3632064

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:49:22
User entered '04 Nov 2020'	Bezuayehu Mandefro (b) (4)	04 Nov 2020 18:17:14

US3632064

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:49:22
User entered '12:48'	Bezuayehu Mandefro (b) (4)	04 Nov 2020 18:17:14

US3632064

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered '04 Nov 2020 12:48'	System	04 Nov 2020 18:17:14

US3632064

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:49:27
User entered 'Yes (Y)'	Bezuayehu Mandefro (b) (4)	04 Nov 2020 18:17:28

US3632064

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered '1'	System	04 Nov 2020 18:17:28

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:06:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:39:30
Data entry locked.	System	09 Sep 2020 19:35:08
User entered 'Day 64'	System	09 Sep 2020 19:35:08

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:06:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:39:30

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:06:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:39:30

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:06:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:39:30

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:06:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:39:30

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:06:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:39:30

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:06:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:39:30

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:06:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:39:30

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:06:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:39:30

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:06:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:39:30

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:06:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:39:30

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:06:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:39:30

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:06:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:39:30

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:06:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:39:30

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:06:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:39:30

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:06:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:39:30

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:06:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:39:30

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:06:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:39:30

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:06:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:39:30

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:06:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:39:30

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:06:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:39:30

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:06:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:39:30

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:06:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:39:30

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:06:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:39:30

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:06:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:39:30

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:06:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:39:30

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:06:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:39:30
Data entry locked.	System	09 Sep 2020 19:35:08
User entered '09 Nov 2020 00:01'	System	09 Sep 2020 19:35:08

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:06:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:39:30
Data entry locked.	System	09 Sep 2020 19:35:08
User entered '13 Nov 2020 23:59'	System	09 Sep 2020 19:35:08

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	09 Sep 2020 19:35:08
User entered 'Day 71'	System	09 Sep 2020 19:35:08

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-11-17T11:24:42', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '02ccd39e-e66b-449d-aac1-9a62771a24ba'	System	17 Nov 2020 16:25:09
User entered 'No (N)'	System	17 Nov 2020 16:25:09

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-11-17T11:24:52', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '02ccd39e-e66b-449d-aac1-9a62771a24ba'	System	17 Nov 2020 16:25:09
User entered 'No (N)'	System	17 Nov 2020 16:25:09

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-11-17T11:25:04', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '02ccd39e-e66b-449d-aac1-9a62771a24ba' User entered '17 Nov 2020 11:25:04'	System	17 Nov 2020 16:25:09
	System	17 Nov 2020 16:25:09

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	09 Sep 2020 19:35:08
User entered '16 Nov 2020 00:01'	System	09 Sep 2020 19:35:08

US3632064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:09:13
Data entry locked.	System	09 Sep 2020 19:35:08
User entered '20 Nov 2020 23:59'	System	09 Sep 2020 19:35:08

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-11-24T15:28:34', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '92a4f43b-d366-42b6-b49e-319657a6fc03' User entered 'No (N)'	System	24 Nov 2020 20:28:58
	System	24 Nov 2020 20:28:58

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-11-24T15:28:41', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '92a4f43b-d366-42b6-b49e-319657a6fc03'	System	24 Nov 2020 20:28:58
User entered 'No (N)'	System	24 Nov 2020 20:28:58

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-11-24T15:28:56', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '92a4f43b-d366-42b6-b49e-319657a6fc03' User entered '24 Nov 2020 15:28:56'	System	24 Nov 2020 20:28:58
	System	24 Nov 2020 20:28:58

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-11-28T11:27:42', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '032f0015-79eb-4d79-8726-7448a6b2ad07'	System	28 Nov 2020 16:28:01
User entered 'No (N)'	System	28 Nov 2020 16:28:01

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-11-28T11:27:46', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '032f0015-79eb-4d79-8726-7448a6b2ad07'	System	28 Nov 2020 16:28:01
User entered 'No (N)'	System	28 Nov 2020 16:28:01

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-11-28T11:27:57', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '032f0015-79eb-4d79-8726-7448a6b2ad07'	System	28 Nov 2020 16:28:01
User entered '28 Nov 2020 11:27:57'	System	28 Nov 2020 16:28:01

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-12-04T09:34:28', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'de783abf-d71b-4f6a-bb3c-90ec229b0691'	System	04 Dec 2020 14:34:59
User entered 'No (N)'	System	04 Dec 2020 14:34:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-12-04T09:34:40', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'de783abf-d71b-4f6a-bb3c-90ec229b0691'	System	04 Dec 2020 14:34:59
User entered 'No (N)'	System	04 Dec 2020 14:34:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-12-04T09:34:55', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'de783abf-d71b-4f6a-bb3c-90ec229b0691' User entered '04 Dec 2020 09:34:55'	System	04 Dec 2020 14:34:59
	System	04 Dec 2020 14:34:59

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-12-11T08:39:37', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'd3d681a1-b76f-4a46-a2e2-0444c5c19cb6'	System	11 Dec 2020 13:40:12
User entered 'No (N)'	System	11 Dec 2020 13:40:12

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-12-11T08:39:49', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'd3d681a1-b76f-4a46-a2e2-0444c5c19cb6'	System	11 Dec 2020 13:40:12
User entered 'No (N)'	System	11 Dec 2020 13:40:12

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-12-11T08:40:07', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'd3d681a1-b76f-4a46-a2e2-0444c5c19cb6'	System	11 Dec 2020 13:40:12
User entered '11 Dec 2020 08:40:07'	System	11 Dec 2020 13:40:12

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-12-18T15:39:21', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'bef205bf-861f-458c-bea6-dbd3359facba'	System	18 Dec 2020 20:39:48
User entered 'No (N)'	System	18 Dec 2020 20:39:48

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-12-18T15:39:37', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'bef205bf-861f-458c-bea6-dbd3359facba'	System	18 Dec 2020 20:39:48
User entered 'No (N)'	System	18 Dec 2020 20:39:48

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-12-18T15:39:46', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'bef205bf-861f-458c-bea6-dbd3359facba' User entered '18 Dec 2020 15:39:46'	System	18 Dec 2020 20:39:48
	System	18 Dec 2020 20:39:48

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-12-26T01:08:53', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'a76ded63-1f07-4820-abb3-bedd897a0ffa'	System	26 Dec 2020 06:09:27
User entered 'No (N)'	System	26 Dec 2020 06:09:27

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-12-26T01:09:08', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'a76ded63-1f07-4820-abb3-bedd897a0ffa'	System	26 Dec 2020 06:09:27
User entered 'No (N)'	System	26 Dec 2020 06:09:27

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2020-12-26T01:09:24', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'a76ded63-1f07-4820-abb3-bedd897a0ffa' User entered '26 Dec 2020 01:09:24'	System	26 Dec 2020 06:09:27
	System	26 Dec 2020 06:09:27

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-01-01T12:40:53', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '769d45cc-0550-45ac-9588-8c022739dfb0'	System	01 Jan 2021 17:43:19
User entered 'Yes (Y)'	System	01 Jan 2021 17:43:19

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-01-01T12:40:58', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '769d45cc-0550-45ac-9588-8c022739dfb0'	System	01 Jan 2021 17:43:19
User entered 'No (N)'	System	01 Jan 2021 17:43:19

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-01-01T12:41:06', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '769d45cc-0550-45ac-9588-8c022739dfb0' User entered 'No (N)'	System	01 Jan 2021 17:43:19

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-01-01T12:41:17', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '769d45cc-0550-45ac-9588-8c022739dfb0'	System	01 Jan 2021 17:43:19
User entered 'Yes (Y)'	System	01 Jan 2021 17:43:19

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-01-01T12:42:54', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '769d45cc-0550-45ac-9588-8c022739dfb0'	System	01 Jan 2021 17:43:19
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Jan 2021 17:43:19

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-01-01T12:43:10', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '769d45cc-0550-45ac-9588-8c022739dfb0' User entered '01 Jan 2021 12:43:10'	System	01 Jan 2021 17:43:19
	System	01 Jan 2021 17:43:19

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-01-08T09:50:54', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'e32b203e-b6f9-4dfb-b96d-b893cccd9ccc'	System	08 Jan 2021 14:52:58
User entered 'Yes (Y)'	System	08 Jan 2021 14:52:58

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-01-08T09:51:07', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'e32b203e-b6f9-4dfb-b96d-b893cccd9ccc'	System	08 Jan 2021 14:52:58
User entered 'No (N)'	System	08 Jan 2021 14:52:58

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-01-08T09:51:15', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'e32b203e-b6f9-4dfb-b96d-b893cccd9ccc'	System	08 Jan 2021 14:52:58
User entered 'No (N)'	System	08 Jan 2021 14:52:58

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-01-08T09:51:29', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'e32b203e-b6f9-4dfb-b96d-b893cccd9ccc' User entered 'Yes (Y)'	System	08 Jan 2021 14:52:58
	System	08 Jan 2021 14:52:58

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-01-08T09:51:55', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'e32b203e-b6f9-4dfb-b96d-b893cccd9ccc'	System	08 Jan 2021 14:52:58
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Jan 2021 14:52:58

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-01-08T09:52:49', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'e32b203e-b6f9-4dfb-b96d-b893cccd9ccc'	System	08 Jan 2021 14:52:58
User entered '08 Jan 2021 09:52:49'	System	08 Jan 2021 14:52:58

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-01-15T07:39:42', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '514b7f74-ce50-434d-94d3-8eeeb2ad7e08'	System	15 Jan 2021 12:40:15
User entered 'No (N)'	System	15 Jan 2021 12:40:15

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-01-15T07:39:53', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '514b7f74-ce50-434d-94d3-8eeeb2ad7e08'	System	15 Jan 2021 12:40:15
User entered 'No (N)'	System	15 Jan 2021 12:40:15

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-01-15T07:40:13', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '514b7f74-ce50-434d-94d3-8eeeb2ad7e08'	System	15 Jan 2021 12:40:15
User entered '15 Jan 2021 07:40:13'	System	15 Jan 2021 12:40:15

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-01-22T16:44:35', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'e107add3-aa47-43c8-93b7-0a474c2e2525'	System	22 Jan 2021 21:44:57
User entered 'No (N)'	System	22 Jan 2021 21:44:57

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-01-22T16:44:45', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'e107add3-aa47-43c8-93b7-0a474c2e2525'	System	22 Jan 2021 21:44:57
User entered 'No (N)'	System	22 Jan 2021 21:44:57

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-01-22T16:44:55', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'e107add3-aa47-43c8-93b7-0a474c2e2525' User entered '22 Jan 2021 16:44:55'	System	22 Jan 2021 21:44:57
	System	22 Jan 2021 21:44:57

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-01-29T08:07:09', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '76849eff-6c81-42d8-89ec-3de887fb11b9'	System	29 Jan 2021 13:07:35
User entered 'No (N)'	System	29 Jan 2021 13:07:35

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-01-29T08:07:24', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '76849eff-6c81-42d8-89ec-3de887fb11b9'	System	29 Jan 2021 13:07:35
User entered 'No (N)'	System	29 Jan 2021 13:07:35

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-01-29T08:07:31', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '76849eff-6c81-42d8-89ec-3de887fb11b9'	System	29 Jan 2021 13:07:35
User entered '29 Jan 2021 08:07:31'	System	29 Jan 2021 13:07:35

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-02-08T01:38:01', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '1d145c57-fc68-435f-bc86-4e24bfa7692b'	System	08 Feb 2021 06:38:16
User entered 'No (N)'	System	08 Feb 2021 06:38:16

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-02-08T01:38:05', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '1d145c57-fc68-435f-bc86-4e24bfa7692b'	System	08 Feb 2021 06:38:16
User entered 'No (N)'	System	08 Feb 2021 06:38:16

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-02-08T01:38:11', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '1d145c57-fc68-435f-bc86-4e24bfa7692b'	System	08 Feb 2021 06:38:16
User entered '08 Feb 2021 01:38:11'	System	08 Feb 2021 06:38:16

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-02-12T07:23:48', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '18f3fc50-90ea-4e1d-82c2-eadeaf79926a'	System	12 Feb 2021 12:24:17
User entered 'No (N)'	System	12 Feb 2021 12:24:17

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-02-12T07:24:03', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '18f3fc50-90ea-4e1d-82c2-eadeaf79926a' User entered 'No (N)'	System	12 Feb 2021 12:24:17

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-02-12T07:24:14', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '18f3fc50-90ea-4e1d-82c2-eadeaf79926a' User entered '12 Feb 2021 07:24:14'	System	12 Feb 2021 12:24:17
	System	12 Feb 2021 12:24:17

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-02-19T13:30:50', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'deb78e64-51ce-4163-ba78-28b09229e5de'	System	19 Feb 2021 18:31:36
User entered 'No (N)'	System	19 Feb 2021 18:31:36

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-02-19T13:31:14', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'deb78e64-51ce-4163-ba78-28b09229e5de'	System	19 Feb 2021 18:31:36
User entered 'No (N)'	System	19 Feb 2021 18:31:36

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-02-19T13:31:33', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'deb78e64-51ce-4163-ba78-28b09229e5de' User entered '19 Feb 2021 13:31:33'	System	19 Feb 2021 18:31:36
	System	19 Feb 2021 18:31:36

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-02-26T11:47:32-05:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'f5289829-430b-422f-b53f-d8de41c7b651'	System	26 Feb 2021 16:48:09
User entered 'No (N)'	System	26 Feb 2021 16:48:09

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-02-26T11:47:41-05:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'f5289829-430b-422f-b53f-d8de41c7b651'	System	26 Feb 2021 16:48:09
User entered 'No (N)'	System	26 Feb 2021 16:48:09

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-02-26T11:47:53-05:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'f5289829-430b-422f-b53f-d8de41c7b651'	System	26 Feb 2021 16:48:09
User entered '26 Feb 2021 16:47:53'	System	26 Feb 2021 16:48:09

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-03-05T09:49:22-05:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '3c0506f5-eda6-4623-8f78-f3ca102da1ed'	System	05 Mar 2021 14:49:52
User entered 'No (N)'	System	05 Mar 2021 14:49:52

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-03-05T09:49:31-05:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '3c0506f5-eda6-4623-8f78-f3ca102da1ed'	System	05 Mar 2021 14:49:52
User entered 'No (N)'	System	05 Mar 2021 14:49:52

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-03-05T09:49:47-05:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '3c0506f5-eda6-4623-8f78-f3ca102da1ed' User entered '05 Mar 2021 09:49:47'	System	05 Mar 2021 14:49:52
	System	05 Mar 2021 14:49:52

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-03-12T09:16:00-05:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '77fe4df0-cb27-43bb-98a0-dc1fb927f6ca'	System	12 Mar 2021 14:16:22
User entered 'No (N)'	System	12 Mar 2021 14:16:22

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-03-12T09:16:09-05:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '77fe4df0-cb27-43bb-98a0-dc1fb927f6ca'	System	12 Mar 2021 14:16:22
User entered 'No (N)'	System	12 Mar 2021 14:16:22

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-03-12T09:16:19-05:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '77fe4df0-cb27-43bb-98a0-dc1fb927f6ca' User entered '12 Mar 2021 09:16:19'	System	12 Mar 2021 14:16:22
	System	12 Mar 2021 14:16:22

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-03-21T13:24:06-04:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '6c5712f1-86a4-44da-b1af-fc8768befbb0'	System	21 Mar 2021 17:24:38
User entered 'No (N)'	System	21 Mar 2021 17:24:38

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-03-21T13:24:15-04:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '6c5712f1-86a4-44da-b1af-fc8768befbb0'	System	21 Mar 2021 17:24:38
User entered 'No (N)'	System	21 Mar 2021 17:24:38

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-03-21T13:24:33-04:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '6c5712f1-86a4-44da-b1af-fc8768befbb0' User entered '21 Mar 2021 13:24:33'	System	21 Mar 2021 17:24:38
	System	21 Mar 2021 17:24:38

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-03-26T22:11:44-04:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '5e9d14b6-4ac5-4737-a232-ac2e30288117'	System	27 Mar 2021 02:13:20
User entered 'No (N)'	System	27 Mar 2021 02:13:20

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-03-26T22:11:52-04:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '5e9d14b6-4ac5-4737-a232-ac2e30288117'	System	27 Mar 2021 02:13:20
User entered 'No (N)'	System	27 Mar 2021 02:13:20

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-03-26T22:12:04-04:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '5e9d14b6-4ac5-4737-a232-ac2e30288117'	System	27 Mar 2021 02:13:20
User entered '26 Mar 2021 22:12:04'	System	27 Mar 2021 02:13:20

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-04-04T18:37:21-04:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'eee9d7e3-6f7d-46f1-a868-5c78600dcd5b'	System	04 Apr 2021 22:37:35
User entered 'No (N)'	System	04 Apr 2021 22:37:35

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-04-04T18:37:24-04:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'eee9d7e3-6f7d-46f1-a868-5c78600dcd5b'	System	04 Apr 2021 22:37:35
User entered 'No (N)'	System	04 Apr 2021 22:37:35

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-04-04T18:37:27-04:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: 'eee9d7e3-6f7d-46f1-a868-5c78600dcd5b' User entered '04 Apr 2021 18:37:27'	System	04 Apr 2021 22:37:35
	System	04 Apr 2021 22:37:35

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-04-09T12:14:24-04:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '640fd3ff-1d5b-4aad-b752-317f01b2155d'	System	09 Apr 2021 16:17:11
User entered 'No (N)'	System	09 Apr 2021 16:17:11

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-04-09T12:14:35-04:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '640fd3ff-1d5b-4aad-b752-317f01b2155d'	System	09 Apr 2021 16:17:11
User entered 'No (N)'	System	09 Apr 2021 16:17:11

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-04-09T12:14:44-04:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '640fd3ff-1d5b-4aad-b752-317f01b2155d'	System	09 Apr 2021 16:17:11
User entered '09 Apr 2021 12:14:44'	System	09 Apr 2021 16:17:11

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-04-16T13:09:39-04:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '8f74709f-3545-4955-800e-f3851d8c53e4'	System	16 Apr 2021 17:13:44
User entered 'No (N)'	System	16 Apr 2021 17:13:44

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-04-16T13:09:48-04:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '8f74709f-3545-4955-800e-f3851d8c53e4'	System	16 Apr 2021 17:13:44
User entered 'No (N)'	System	16 Apr 2021 17:13:44

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-04-16T13:09:56-04:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '8f74709f-3545-4955-800e-f3851d8c53e4'	System	16 Apr 2021 17:13:44
User entered '16 Apr 2021 13:09:56'	System	16 Apr 2021 17:13:44

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-04-23T11:09:11-04:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '0c479c6e-416c-487a-ace9-1d4e02c13037'	System	23 Apr 2021 15:09:31
User entered 'No (N)'	System	23 Apr 2021 15:09:31

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-04-23T11:09:18-04:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '0c479c6e-416c-487a-ace9-1d4e02c13037'	System	23 Apr 2021 15:09:31
User entered 'No (N)'	System	23 Apr 2021 15:09:31

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-04-23T11:09:28-04:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '0c479c6e-416c-487a-ace9-1d4e02c13037'	System	23 Apr 2021 15:09:31
User entered '23 Apr 2021 11:09:28'	System	23 Apr 2021 15:09:31

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-04-30T19:28:00-04:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '14b314fa-8ef4-417b-b054-11c666f07f77'	System	30 Apr 2021 23:28:20
User entered 'No (N)'	System	30 Apr 2021 23:28:20

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-04-30T19:28:07-04:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '14b314fa-8ef4-417b-b054-11c666f07f77'	System	30 Apr 2021 23:28:20
User entered 'No (N)'	System	30 Apr 2021 23:28:20

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-04-30T19:28:14-04:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '14b314fa-8ef4-417b-b054-11c666f07f77'	System	30 Apr 2021 23:28:20
User entered '30 Apr 2021 19:28:14'	System	30 Apr 2021 23:28:20

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 06:39:30

US3632064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:39:30
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 06:39:30

US3632064

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:14:39

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-03-05T09:50:08-05:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '4b433bb7-e915-4e7a-9a1c-96583ef9ec6e'	System	05 Mar 2021 14:50:20
User entered 'No (N)'	System	05 Mar 2021 14:50:20

US3632064

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:14:39

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07A68026-0A9A-4013-A6AC-038756CBC513)', Time: '2021-03-05T09:50:16-05:00', User OID: 'PatientReportedOutcome (US3632064)', ODM File OID: '4b433bb7-e915-4e7a-9a1c-96583ef9ec6e' User entered '05 Mar 2021 09:50:16'	System	05 Mar 2021 14:50:20
	System	05 Mar 2021 14:50:20

US3632064

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:50:09
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	02 Dec 2020 20:00:52

US3632064

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:50:09
User entered '2 Dec 2020'	Kelly Likos (b) (4) (b) (4)	02 Dec 2020 20:00:52

US3632064

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:50:09
User entered 'Contact Made (CONTACT MADE)'	Kelly Likos (b) (4) (b) (4)	02 Dec 2020 20:00:52

US3632064

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:50:09
User entered empty.	Kelly Likos (b) (4) (b) (4)	02 Dec 2020 20:00:52

US3632064

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:50:20
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	02 Dec 2020 20:01:04

US3632064

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:56
User entered '1'	System	02 Dec 2020 20:01:04

US3632064

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:50:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:34:07
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	04 Feb 2021 21:48:31
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Feb 2021 21:48:31
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	04 Feb 2021 21:47:14
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	04 Feb 2021 21:47:14
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Feb 2021 21:47:14
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	04 Feb 2021 21:45:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 21:45:26

US3632064

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:50:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:34:07
User entered '5 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Feb 2021 21:48:25
User closed query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	04 Feb 2021 21:45:51
Query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	04 Feb 2021 21:45:51
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	04 Feb 2021 21:45:51
User opened query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	04 Feb 2021 21:45:26
User entered '4 Feb 2021'	(b) (4), (b) (6)	04 Feb 2021 21:45:26

US3632064

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:50:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:34:07
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Feb 2021 21:47:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Feb 2021 21:45:26

US3632064

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:50:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:34:07
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	04 Feb 2021 21:48:25
User entered 'participant was hospitale when SC was due for TIA/CVA, records have been sent' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Feb 2021 21:48:25
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	04 Feb 2021 21:47:14
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 21:45:26

US3632064

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:50:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:35:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 21:48:35

US3632064

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:50:22
User entered '1'	System	04 Feb 2021 21:48:35

US3632064

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:50:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:38:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 21:48:52

US3632064

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:50:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:38:01
User entered '4 Feb 2021'	(b) (4), (b) (6)	04 Feb 2021 21:48:52

US3632064

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:50:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:38:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Feb 2021 21:48:52

US3632064

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:50:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:38:01
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 21:48:52

US3632064

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:50:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:38:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 21:48:56

US3632064

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:50:22
User entered '1'	System	04 Feb 2021 21:48:56

US3632064

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:38:36
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Mar 2021 20:53:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Mar 2021 20:53:12
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 20:53:12
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 19:33:17
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:33:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 18:52:17

US3632064

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:27:21
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
User entered '5 Mar 2021' reason for change: Data Entry Error	Kelly Likos (b) (4)	29 Mar 2021 18:14:04
DataPoint Un-verified.	(b) (4), (b) (6)	26 Mar 2021 18:39:15
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 18:38:36
User entered '8 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 20:53:45
User entered '5 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 20:53:12
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:33:17
User entered '05 Mar 2021'	(b) (4), (b) (6)	05 Mar 2021 18:52:17

US3632064

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:38:36
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 20:53:12
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:33:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Mar 2021 18:52:17

US3632064

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:38:36
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 18:52:17

US3632064

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:40:40
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Mar 2021 20:53:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Mar 2021 20:53:17
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 20:53:17
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 19:33:22
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:33:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 18:52:23

US3632064

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:16:08
User entered '1'	System	08 Mar 2021 20:53:17
User entered empty.	System	05 Mar 2021 19:33:22
User entered '1'	System	05 Mar 2021 18:52:23

US3632064

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 18:53:32

US3632064

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:27
User entered '05 Apr 2021'	(b) (4), (b) (6)	05 Apr 2021 18:53:32

US3632064

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:27
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	05 Apr 2021 18:53:32

US3632064

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:07
User entered 'VISIT4'	System	05 Apr 2021 18:53:32

US3632064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:41
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 18:53:43

US3632064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:41
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 18:53:43

US3632064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:41
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 18:53:43

US3632064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:07
User entered empty.	System	05 Apr 2021 18:53:43

US3632064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:41
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 18:53:43

US3632064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:41
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 18:53:43

US3632064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:41
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 18:53:43

US3632064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:41
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 18:53:43

US3632064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:07
User entered empty.	System	05 Apr 2021 18:53:43

US3632064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:41
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 18:53:43

US3632064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:07
User entered empty.	System	05 Apr 2021 18:53:43

US3632064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:41
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 18:53:43

US3632064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:07
User entered empty.	System	05 Apr 2021 18:53:43

US3632064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:41
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 18:53:43

US3632064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:07
User entered empty.	System	05 Apr 2021 18:53:43

US3632064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:07

US3632064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:39

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:07

US3632064

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:14:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:48
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 18:53:59

US3632064

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:14:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:48
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 18:53:59

US3632064

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 18:54:40

US3632064

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:53
User entered '05 Apr 2021'	(b) (4), (b) (6)	05 Apr 2021 18:54:40

US3632064

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:53
User entered '13:34'	(b) (4), (b) (6)	05 Apr 2021 18:54:40

US3632064

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:07
User entered '05 Apr 2021 13:34'	System	05 Apr 2021 18:54:40

US3632064

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:07
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:21:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 18:54:51

US3632064

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:56:07
User entered '1'	System	05 Apr 2021 18:54:51

US3632064

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

Form: Visit Date

Generated On: 10 Jun 2021 09:14:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:35:56
User entered 'Yes (Y)'	Catherine Abrams (b) (4)	08 Jan 2021 18:27:20
	(b) (4)	

US3632064

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

Form: Visit Date

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:35:56
User entered '8 Jan 2021'	Catherine Abrams (b) (4)	08 Jan 2021 18:27:20
	(b) (4)	

US3632064

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

Form: Visit Date

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:35:56
User entered 'Clinic (Clinic)'	Catherine Abrams (b) (4)	08 Jan 2021 18:27:20
	(b) (4)	

US3632064

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

Form: Visit Date

Generated On: 10 Jun 2021 09:14:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered 'UNBLND_DECIDE'	System	08 Jan 2021 18:27:20

US3632064

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

Form: Unblinding

Generated On: 10 Jun 2021 09:14:39

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:36:02
User entered '8 Jan 2021'	Catherine Abrams (b) (4)	08 Jan 2021 18:27:42
	(b) (4)	

US3632064

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

Form: Unblinding

Generated On: 10 Jun 2021 09:14:39

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:04:50
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
User entered '0'	(b) (4) Aastha KC (b) (4)	31 Mar 2021 15:39:27
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 08:41:30

US3632064

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

Form: Unblinding

Generated On: 10 Jun 2021 09:14:39

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:36:02
User entered 'Yes (Y)'	Catherine Abrams (b) (4)	08 Jan 2021 18:27:42
	(b) (4)	

US3632064

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

Form: Unblinding

Generated On: 10 Jun 2021 09:14:39

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:04:50
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4)	
	Aastha KC (b) (4)	31 Mar 2021 15:39:27
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:41:30

US3632064

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

Form: Unblinding

Generated On: 10 Jun 2021 09:14:39

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:36:02
User entered '8 Jan 2021'	Catherine Abrams (b) (4)	08 Jan 2021 18:27:42
	(b) (4)	

US3632064

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

Form: Unblinding

Generated On: 10 Jun 2021 09:14:39

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:36:02
User entered 'mRNA-1273 (mRNA-1273)'	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:27:42

US3632064

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

Form: Unblinding

Generated On: 10 Jun 2021 09:14:39

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:36:02
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 09:15:29
User entered 'mRNA-1273 (mRNA-1273)'	Catherine Abrams (b) (4)	08 Jan 2021 18:27:42
	(b) (4)	

US3632064

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

Form: Unblinding

Generated On: 10 Jun 2021 09:14:39

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:36:02
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 09:15:29
User entered 'mRNA-1273 (mRNA-1273)'	Catherine Abrams (b) (4)	08 Jan 2021 18:27:42
	(b) (4)	

US3632064

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

Form: Unblinding

Generated On: 10 Jun 2021 09:14:39

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:36:02
User entered 'No (N)'	Catherine Abrams (b) (4)	08 Jan 2021 18:27:42
	(b) (4)	

US3632064

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

Form: Unblinding

Generated On: 10 Jun 2021 09:14:39

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered empty.	System	08 Jan 2021 18:27:42

US3632064

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

Form: Unblinding

Generated On: 10 Jun 2021 09:14:39

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered empty.	System	08 Jan 2021 18:27:42

US3632064

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:36:32
User entered 'Yes (Y)'	Catherine Abrams (b) (4)	08 Jan 2021 18:30:13
	(b) (4)	

US3632064

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:36:32
User entered '8 Jan 2021'	Catherine Abrams (b) (4)	08 Jan 2021 18:30:13
	(b) (4)	

US3632064

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:36:32
User entered '12:37'	Catherine Abrams (b) (4)	08 Jan 2021 18:30:13
	(b) (4)	

US3632064

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered '8 Jan 2021 12:37'	System	08 Jan 2021 18:30:13

US3632064

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:14:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:36:46
User entered 'Yes (Y)'	Catherine Abrams (b) (4)	08 Jan 2021 18:30:36
	(b) (4)	

US3632064

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:14:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:36:46
User entered '8 Jan 2021'	Catherine Abrams (b) (4)	08 Jan 2021 18:30:36
	(b) (4)	

US3632064

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:14:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:36:46
User entered '12:40'	Catherine Abrams (b) (4)	08 Jan 2021 18:30:36
	(b) (4)	

US3632064

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:07:45
User entered '8 Jan 2021 12:40'	System	08 Jan 2021 18:30:36

US3632064

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:14:39

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:04:17
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:10:25
User entered 'Yes (Y)'	Catherine Abrams (b) (4) (b) (4)	01 Jan 2021 18:12:21

US3632064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:15:18
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:36:46
User entered 'USA-US120-2021-mRNA-1273-P301000001'	System	04 Jan 2021 19:36:42
User entered 'New'	(b) (4), (b) (6)	04 Jan 2021 19:36:42

US3632064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:15:19
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Transient cerebrovascular events, PT: Transient ischaemic attack, LLT: Transient ischemic attack - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Jan 2021 18:20:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Jan 2021 18:20:34
Data point term sent to Coder	System	01 Jan 2021 18:19:21
User entered 'transient ischemic attack'	Catherine Abrams (b) (4) (b) (4)	01 Jan 2021 18:19:09

US3632064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:15:21
User entered 'Yes (Y)'	Catherine Abrams (b) (4) (b) (4)	01 Jan 2021 18:19:09

US3632064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:15:23
User entered 'No (N)'	Catherine Abrams (b) (4) (b) (4)	01 Jan 2021 18:19:09

US3632064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:15:25
User entered 'No (N)'	Catherine Abrams (b) (4) (b) (4)	01 Jan 2021 18:19:09

US3632064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:15:29
User entered '31 Dec 2020'	Catherine Abrams (b) (4) (b) (4)	01 Jan 2021 18:19:09

US3632064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:17:43
User entered empty.	Catherine Abrams (b) (4) (b) (4)	01 Jan 2021 18:19:09

US3632064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Jan 2021 18:19:09

US3632064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:17:46
User entered 'No (N)' reason for change: New Information	Christina Bacher (b) (4)	13 Jan 2021 19:54:45
User entered 'Yes (Y)'	Catherine Abrams (b) (4)	01 Jan 2021 18:19:09

US3632064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:18:38
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)	14 Jan 2021 13:44:35
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 'updated' (Site from Safety).	Christina Bacher (b) (4) (b) (4)	13 Jan 2021 19:58:59
User entered '04 Jan 2021' reason for change: New Information	Christina Bacher (b) (4) (b) (4)	13 Jan 2021 19:54:45
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)	11 Jan 2021 18:21:59
User entered empty.	Catherine Abrams (b) (4) (b) (4)	01 Jan 2021 18:19:09

US3632064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:19:08
User entered empty.	Catherine Abrams (b) (4) (b) (4)	01 Jan 2021 18:19:09

US3632064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Jan 2021 18:19:09

US3632064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:44
DataPoint Verified.	(b) (4)	12 Feb 2021 17:25:58
	(b) (4), (b) (6)	
User closed query 'Source notes this as Grade 4 (potentially life threatening); please review/verify and update.' (Site from CRA).	(b) (4), (b) (6)	12 Feb 2021 17:25:55
Query 'Source notes this as Grade 4 (potentially life threatening); please review/verify and update.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 21:38:34
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Feb 2021 21:38:26
User opened query 'Source notes this as Grade 4 (potentially life threatening); please review/verify and update.' (Site from CRA).	(b) (4), (b) (6)	29 Jan 2021 20:17:36
User entered 'Grade 3/Severe (Grade 3/Severe)'	Catherine Abrams (b) (4)	01 Jan 2021 18:19:09
	(b) (4)	

US3632064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:19:11
User entered 'Yes (Y)'	Catherine Abrams (b) (4) (b) (4)	01 Jan 2021 18:19:09

US3632064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:19:14
User entered '0'	Catherine Abrams (b) (4) (b) (4)	01 Jan 2021 18:19:09

US3632064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:19:16
User entered '1'	Catherine Abrams (b) (4) (b) (4)	01 Jan 2021 18:19:09

US3632064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 18:32:05
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:44
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	04 Jan 2021 06:12:02
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Admitted on 12/31/2020 which has been entered as admit date. Still inpatient in the ICU ' (Site from System).	Catherine Abrams (b) (4) (b) (4)	01 Jan 2021 18:26:19
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	01 Jan 2021 18:20:20
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	01 Jan 2021 18:20:20
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	01 Jan 2021 18:20:20
User entered '1' reason for change: Data Entry Error	Catherine Abrams (b) (4) (b) (4)	01 Jan 2021 18:20:20
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	01 Jan 2021 18:19:50
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	01 Jan 2021 18:19:50

US3632064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	01 Jan 2021 18:19:50
User entered '0' reason for change: Data Entry Error	Catherine Abrams (b) (4)	01 Jan 2021 18:19:50
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System (b) (4)	01 Jan 2021 18:19:09
User entered '1'	Catherine Abrams (b) (4)	01 Jan 2021 18:19:09

US3632064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:39:10
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	15 Mar 2021 12:25:44
User entered '31 Dec 2020'	Catherine Abrams (b) (4) (b) (4)	01 Jan 2021 18:19:09

US3632064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:39:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:44
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 Feb 2021 17:48:58
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 'sent in email 20Jan2021' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 21:36:44
User closed query 'Per CDM:Kindly consider to update the Hospital discharge date after the AE is resolved.Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 10:23:42
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 13:44:50
Query 'Per CDM:Kindly consider to update the Hospital discharge date after the AE is resolved.Thank you.' answered with 'AE resolved with sequelae' (Site from DM).	Christina Bacher (b) (4)	13 Jan 2021 19:56:42
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety).	Christina Bacher (b) (4)	13 Jan 2021 19:56:10
User entered '4 Jan 2021' reason for change: New Information	Catherine Abrams (b) (4)	13 Jan 2021 19:15:27
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)	11 Jan 2021 18:21:47
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 18:21:34

US3632064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User opened query 'Per CDM:Kindly consider to update the Hospital discharge date after the AE is resolved.Thank you.' (Site from DM). User entered empty.	(b) (4), (b) (6)	04 Jan 2021 06:13:54
	Catherine Abrams (b) (4)	01 Jan 2021 18:19:09
	(b) (4)	

US3632064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:55:20
DataPoint Un-verified.	(b) (4), (b) (6)	29 Jan 2021 20:22:22
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:20:08
User entered 'Yes (Y)'	Catherine Abrams (b) (4) (b) (4)	01 Jan 2021 18:19:09

US3632064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:55:22
User entered '1' reason for change: New Information	Catherine Abrams (b) (4)	13 Jan 2021 15:18:16
User closed query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	(b) (4) System	01 Jan 2021 18:20:20
Query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' answered by data change (Site from System).	System	01 Jan 2021 18:20:20
User opened query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	01 Jan 2021 18:19:50
User closed query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	01 Jan 2021 18:19:50
Query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' answered by data change (Site from System).	System	01 Jan 2021 18:19:50
User entered '2' reason for change: New Information	Catherine Abrams (b) (4)	01 Jan 2021 18:19:50
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	(b) (4) System	01 Jan 2021 18:19:09
User entered empty.	Catherine Abrams (b) (4)	01 Jan 2021 18:19:09

US3632064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:22:26
User entered '0'	Catherine Abrams (b) (4) (b) (4)	01 Jan 2021 18:19:09

US3632064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:22:29
User entered '0'	Catherine Abrams (b) (4) (b) (4)	01 Jan 2021 18:19:09

US3632064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:22:30
User entered '0'	Catherine Abrams (b) (4) (b) (4)	01 Jan 2021 18:19:09

US3632064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:22:33
User entered 'Not Related (NOT RELATED)'	Catherine Abrams (b) (4) (b) (4)	01 Jan 2021 18:19:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:22:35
User entered 'Not Related (NOT RELATED)'	Catherine Abrams (b) (4) (b) (4)	01 Jan 2021 18:19:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:22:39
User closed query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 10:22:05
User closed query 'PV Query: As the last dose of the study drug was given on 07 Oct 2020, please update the action taken with the study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 22:20:54
Query 'PV Query: As the last dose of the study drug was given on 07 Oct 2020, please update the action taken with the study drug from none to not applicable.' answered with 'updated ' (Site from Safety).	Catherine Abrams (b) (4)	13 Jan 2021 15:20:12
Query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' answered with 'updated ' (Site from DM).	Catherine Abrams (b) (4)	13 Jan 2021 15:20:08
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: New Information	Catherine Abrams (b) (4)	13 Jan 2021 15:19:01
User opened query 'PV Query: As the last dose of the study drug was given on 07 Oct 2020, please update the action taken with the study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 18:21:08
User opened query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 14:45:32
User entered 'None (NONE)'	Catherine Abrams (b) (4)	01 Jan 2021 18:19:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:22:42
User entered '0'	Catherine Abrams (b) (4) (b) (4)	01 Jan 2021 18:19:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:22:48
User entered '1'	Catherine Abrams (b) (4) (b) (4)	01 Jan 2021 18:19:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 18:32:28
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:44
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 17:03:47
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken. ' answered with 'Diagnostic Procedures have been removed from Con Proc log and selection has been updated.' (Site from DM).	Isaac Perez (b) (4)	15 Feb 2021 14:15:53
DataPoint Un-verified.	Isaac Perez (b) (4)	15 Feb 2021 14:15:26
User entered '0' reason for change: Data Entry Error	Isaac Perez (b) (4)	15 Feb 2021 14:15:26
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 01:06:07
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:22:50
User entered '1'	Catherine Abrams (b) (4)	01 Jan 2021 18:19:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Jan 2021 20:22:53
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 13:45:04
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'resolved with sequelae of right sided weakness' (Site from Safety).	Christina Bacher (b) (4)	13 Jan 2021 19:59:41
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	Christina Bacher (b) (4)	13 Jan 2021 19:54:45
reason for change: Data Entry Error	(b) (4), (b) (6)	
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 18:22:38
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Catherine Abrams (b) (4)	01 Jan 2021 18:19:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

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

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:22:56
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	13 Jan 2021 19:58:44
User entered 'Participant continues to have right sided weakness, but ambulates without assistance.' reason for change: New Information	Christina Bacher (b) (4) (b) (4)	13 Jan 2021 19:58:44
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	13 Jan 2021 19:54:45
User entered empty.	Catherine Abrams (b) (4) (b) (4)	01 Jan 2021 18:19:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:39:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:25:44
User closed query 'Per DM CLR: Narrative = MRI 03JAN2021 . However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:22:34
Query 'Per DM CLR: Narrative = MRI 03JAN2021 . However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'MRI added to eCRF and source. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 19:04:42
User opened query 'Per DM CLR: Narrative = MRI 03JAN2021 . However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 02:26:27
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 Feb 2021 17:48:54
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 17:48:50
User closed query 'PV Query: Please consider updating the event term based on the results of the brain MRI from 03Jan2021 noting findings "compatible with acute to subacute infarct."' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 17:48:49
Query 'PV Query: Please consider updating the event term based on the results of the brain MRI from 03Jan2021 noting findings "compatible with acute to subacute infarct."' answered with 'updated as requested' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 21:38:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

[Narrative](#)

Audit	User	Time (GMT)
User entered 'ADMITTED TO ICU ON 12/31/2020 DUE TO TIA WITH SLURRED SPEECH AND RIGHT HAND WEAKNESS. GIVEN PLAXIS. ON 01/01/2021 CLEAR SPEECH AND RIGHT HAND STRENGTH RESOLVING. MRI 03Jan2021 with findings compatible with acute to subacute infarct' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Feb 2021 21:38:26
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'sent to email on 20Jan2021' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 21:37:27
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 'not done' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 21:37:17
User opened query 'PV Query: Please consider updating the event term based on the results of the brain MRI from 03Jan2021 noting findings "compatible with acute to subacute infarct."' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 18:55:29
User closed query 'PV Query: Please provide an alternate etiology for the event of transient ischemic attack.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 13:45:19
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 22:21:08
Query 'PV Query: Please provide an alternate etiology for the event of transient ischemic attack.' answered with 'See risk factors in medical history. ' (Site from Safety).	Christina Bacher (b) (4)	13 Jan 2021 19:58:33
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' answered with 'severe obesity high cholesterol high blood pressure ' (Site from Safety).	Catherine Abrams (b) (4)	13 Jan 2021 15:27:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide an alternate etiology for the event of transient ischemic attack.' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 18:23:11
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 18:22:27
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 18:22:14
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)	11 Jan 2021 18:21:22
User entered 'admitted to ICU on 12/31/2020 due to TIA with slurred speech and right hand weakness. Given plaxis. on 01/01/2021 clear speech and right hand strength resolving'	Catherine Abrams (b) (4)	01 Jan 2021 18:19:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	01 Jan 2021 18:19:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	01 Jan 2021 18:19:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Jan 2021 18:19:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:14:39

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:04:17
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:25:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 15:31:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:24:28
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: MIRABEGRON - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 07:55:43
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 Sep 2020 07:55:43
Data point term sent to Coder	System	10 Sep 2020 15:37:28
User entered 'Mirabegron'	(b) (4), (b) (6)	10 Sep 2020 15:36:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:24:28
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 15:36:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:24:28
User entered 'Prostate and Bladder Issues'	(b) (4), (b) (6)	10 Sep 2020 15:36:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:24:28
User entered '50'	(b) (4), (b) (6)	10 Sep 2020 15:36:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:24:28
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Sep 2020 15:36:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:24:28
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:36:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:24:28
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Sep 2020 15:36:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:24:28
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:36:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:24:28
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Sep 2020 15:36:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:24:28
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:36:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:24:28
User entered '14 Jul 2020'	(b) (4), (b) (6)	10 Sep 2020 15:36:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:24:28
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:36:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:24:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 15:36:48

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:24:28
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:36:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:24:28
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 15:36:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 15:36:48

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 15:36:48

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 15:36:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:29
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:24:51
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: PRAVASTATIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:39:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:39:36
Data point term sent to Coder	System	10 Sep 2020 15:38:34
User entered 'Pravastatin '	(b) (4), (b) (6)	10 Sep 2020 15:37:37

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:29
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:24:51
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 15:37:37

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:29
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:24:51
User entered 'High Cholesterol'	(b) (4), (b) (6)	10 Sep 2020 15:37:37

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:29
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:24:51
User entered '40'	(b) (4), (b) (6)	10 Sep 2020 15:37:37

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:29
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:24:51
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Sep 2020 15:37:37

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:29
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:24:51
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:37:37

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:29
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:24:51
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Sep 2020 15:37:37

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:29
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:24:51
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:37:37

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:29
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:24:51
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Sep 2020 15:37:37

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:29
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:24:51
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:37:37

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:36
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Un-verified.	(b) (4) Isaac Perez (b) (4)	30 Mar 2021 19:18:27
User entered 'UN UNK 2015' reason for change: Data Entry Error	(b) (4) Isaac Perez (b) (4)	30 Mar 2021 19:18:27
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 19:24:51
User entered '1 UNK 2015'	(b) (4), (b) (6)	10 Sep 2020 15:37:37

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:29
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:24:51
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:37:37

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:29
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:24:51
User entered 'No (N)' reason for change: New Information	Catherine Abrams (b) (4)	08 Jan 2021 18:40:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 15:37:37

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:29
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:24:51
User entered '4 Jan 2021' reason for change: New Information	Catherine Abrams (b) (4)	08 Jan 2021 18:40:47
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:37:37

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:29
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:24:51
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 15:37:37

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:29
User entered '1'	System	10 Sep 2020 15:37:37

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:29
User entered '1'	System	10 Sep 2020 15:37:37

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:29
User entered '804 (804)'	System	10 Sep 2020 15:37:37

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:26:21
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS, PRODUCT: FINASTERIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:51:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:51:47
Data point term sent to Coder	System	10 Sep 2020 15:38:35
User entered 'Finasteride'	(b) (4), (b) (6)	10 Sep 2020 15:38:13

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:26:21
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 15:38:13

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:26:21
User entered 'Prostate and Bladder Issues'	(b) (4), (b) (6)	10 Sep 2020 15:38:13

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:26:21
User entered '5'	(b) (4), (b) (6)	10 Sep 2020 15:38:13

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:26:21
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Sep 2020 15:38:13

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:26:21
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:38:13

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:26:21
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Sep 2020 15:38:13

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:26:21
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:38:13

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:26:21
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Sep 2020 15:38:13

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:26:21
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:38:13

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:36
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Un-verified.	(b) (4)	
	Isaac Perez (b) (4)	30 Mar 2021 19:18:45
User entered 'UN UNK 2018' reason for change:	(b) (4)	
Data Entry Error	Isaac Perez (b) (4)	30 Mar 2021 19:18:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Feb 2021 19:26:21
User entered '1 UNK 2018'	(b) (4), (b) (6)	10 Sep 2020 15:38:13

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:26:21
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:38:13

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:26:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 15:38:13

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:26:21
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:38:13

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:26:21
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 15:38:13

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 15:38:13

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 15:38:13

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 15:38:13

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:30:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:41:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:41:43
Data point term sent to Coder	System	10 Sep 2020 15:40:40
User entered 'Amlodipine'	(b) (4), (b) (6)	10 Sep 2020 15:39:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:30:09
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 15:39:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:30:09
User entered 'High Blood Pressure'	(b) (4), (b) (6)	10 Sep 2020 15:39:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:30:09
User entered '5'	(b) (4), (b) (6)	10 Sep 2020 15:39:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:30:09
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Sep 2020 15:39:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:30:09
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:39:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:30:09
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Sep 2020 15:39:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:30:09
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:39:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:30:09
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Sep 2020 15:39:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:30:09
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:39:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:36
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Un-verified.	(b) (4)	
	Isaac Perez (b) (4)	30 Mar 2021 19:19:03
User entered 'UN UNK 2010' reason for change:	(b) (4)	
Data Entry Error	Isaac Perez (b) (4)	30 Mar 2021 19:19:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Feb 2021 19:30:09
User entered '1 UNK 2010'	(b) (4), (b) (6)	10 Sep 2020 15:39:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:30:09
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:39:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:30:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 15:39:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:30:09
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:39:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:30:09
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 15:39:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 15:39:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 15:39:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 15:39:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:32:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTI-PARKINSON DRUGS, ATC: DOPAMINERGIC AGENTS, ATC: DOPA AND DOPA DERIVATIVES, PRODUCT: CARBIDOPA;LEVODOPA, PRODUCTSYNONYM: CARBIDOPA LEVODOPA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:42:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:42:41
Data point term sent to Coder	System	10 Sep 2020 15:41:41
User entered 'Carbidopa Levodopa'	(b) (4), (b) (6)	10 Sep 2020 15:40:50

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:32:48
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 15:40:50

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:32:48
User entered 'Parkinson's Disease'	(b) (4), (b) (6)	10 Sep 2020 15:40:50

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:32:48
User entered '25-100'	(b) (4), (b) (6)	10 Sep 2020 15:40:50

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:32:48
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Sep 2020 15:40:50

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:32:48
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:40:50

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:32:48
User entered 'three times daily (TID)'	(b) (4), (b) (6)	10 Sep 2020 15:40:50

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:32:48
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:40:50

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:32:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Sep 2020 15:40:50

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:32:48
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:40:50

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:32:48
User entered '2 Dec 2019'	(b) (4), (b) (6)	10 Sep 2020 15:40:50

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:32:48
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:40:50

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:32:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 15:40:50

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:32:48
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:40:50

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:32:48
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 15:40:50

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	10 Sep 2020 15:40:50

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 15:40:50

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 15:40:50

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:47
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: IRBESARTAN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:43:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:43:41
Data point term sent to Coder User entered 'Irbesartan'	System (b) (4), (b) (6)	10 Sep 2020 15:42:43 10 Sep 2020 15:41:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:47
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 15:41:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:47
User entered 'High Blood Pressure'	(b) (4), (b) (6)	10 Sep 2020 15:41:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:47
User entered '300'	(b) (4), (b) (6)	10 Sep 2020 15:41:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:47
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Sep 2020 15:41:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:47
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:41:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:47
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Sep 2020 15:41:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:47
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:41:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:47
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Sep 2020 15:41:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:47
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:41:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:36
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Un-verified.	(b) (4)	
	Isaac Perez (b) (4)	30 Mar 2021 19:19:40
User entered 'UN UNK 2015' reason for change:	(b) (4)	
Data Entry Error	Isaac Perez (b) (4)	30 Mar 2021 19:19:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Feb 2021 19:33:47
User entered '1 UNK 2015'	(b) (4), (b) (6)	10 Sep 2020 15:41:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:47
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:41:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 15:41:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:47
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:41:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:47
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 15:41:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 15:41:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 15:41:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 15:41:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:52
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:43:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:43:41
Data point term sent to Coder User entered 'Metoprolol'	System (b) (4), (b) (6)	10 Sep 2020 15:42:42 10 Sep 2020 15:42:16

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:52
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 15:42:16

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:52
User entered 'High Blood Pressure'	(b) (4), (b) (6)	10 Sep 2020 15:42:16

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:52
User entered '100'	(b) (4), (b) (6)	10 Sep 2020 15:42:16

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:52
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Sep 2020 15:42:16

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:52
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:42:16

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:52
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Sep 2020 15:42:16

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:52
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:42:16

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:52
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Sep 2020 15:42:16

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:52
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:42:16

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:36
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Un-verified.	(b) (4)	
	Isaac Perez (b) (4)	30 Mar 2021 19:19:58
User entered 'UN UNK 2015' reason for change:	(b) (4)	
Data Entry Error	Isaac Perez (b) (4)	30 Mar 2021 19:19:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Feb 2021 19:33:52
User entered '1 UNK 2015'	(b) (4), (b) (6)	10 Sep 2020 15:42:16

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:52
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:42:16

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 15:42:16

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:52
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:42:16

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:52
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 15:42:16

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 15:42:16

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 15:42:16

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 15:42:16

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:55
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) (b) (4)	11 Sep 2020 08:00:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 08:00:52
Data point term sent to Coder	System	10 Sep 2020 15:43:44
User entered 'Tamsulosin'	(b) (4), (b) (6)	10 Sep 2020 15:42:46

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:55
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 15:42:46

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:55
User entered 'Prostate and Bladder Issues'	(b) (4), (b) (6)	10 Sep 2020 15:42:46

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:55
User entered '0.4'	(b) (4), (b) (6)	10 Sep 2020 15:42:46

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:55
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Sep 2020 15:42:46

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:55
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:42:46

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:55
User entered 'twice daily (BID)'	(b) (4), (b) (6)	10 Sep 2020 15:42:46

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:55
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:42:46

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:55
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Sep 2020 15:42:46

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:55
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:42:46

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:36
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Un-verified.	(b) (4)	
	Isaac Perez (b) (4)	30 Mar 2021 19:20:24
User entered 'UN UNK 2018' reason for change:	(b) (4)	
Data Entry Error	Isaac Perez (b) (4)	30 Mar 2021 19:20:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Feb 2021 19:33:55
User entered '1 UNK 2018'	(b) (4), (b) (6)	10 Sep 2020 15:42:46

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:55
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:42:46

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 15:42:46

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:55
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:42:46

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:33:55
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 15:42:46

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	10 Sep 2020 15:42:46

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 15:42:46

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 15:42:46

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:34:00
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:44:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:44:42
Data point term sent to Coder User entered 'Hydrochlorothiazide '	System (b) (4), (b) (6)	10 Sep 2020 15:43:45 10 Sep 2020 15:43:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:34:00
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 15:43:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:34:00
User entered 'High Blood Pressure'	(b) (4), (b) (6)	10 Sep 2020 15:43:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:34:00
User entered '25'	(b) (4), (b) (6)	10 Sep 2020 15:43:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:34:00
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Sep 2020 15:43:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:34:00
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:43:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:34:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Sep 2020 15:43:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:34:00
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:43:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:34:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Sep 2020 15:43:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:34:00
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:43:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:36
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Un-verified.	(b) (4)	
	Isaac Perez (b) (4)	30 Mar 2021 19:20:45
User entered 'UN UNK 2015' reason for change:	(b) (4)	
Data Entry Error	Isaac Perez (b) (4)	30 Mar 2021 19:20:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Feb 2021 19:34:00
User entered '1 UNK 2015'	(b) (4), (b) (6)	10 Sep 2020 15:43:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:34:00
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:43:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:34:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 15:43:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:34:00
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:43:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:34:00
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 15:43:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 15:43:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 15:43:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 15:43:43

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:39

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:34:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:45:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:45:41
Data point term sent to Coder	System	10 Sep 2020 15:44:48
User entered 'Vitamin D'	(b) (4), (b) (6)	10 Sep 2020 15:44:14

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:36
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:21
User closed query 'Per DM CLR: Please review response as vitamins are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 06:02:33
Query 'Per DM CLR: Please review response as vitamins are considered as prophylaxis. Update as appropriate. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 13:47:05
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 13:47:00
Signature has been broken.	(b) (4), (b) (6)	06 Apr 2021 13:47:00
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 13:47:00
User opened query 'Per DM CLR: Please review response as vitamins are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 09:30:20
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 19:34:03
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 15:44:14

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:34:03
User entered 'General Health'	(b) (4), (b) (6)	10 Sep 2020 15:44:14

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:34:03
User entered '1000'	(b) (4), (b) (6)	10 Sep 2020 15:44:14

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:34:03
User entered 'IU (IU)'	(b) (4), (b) (6)	10 Sep 2020 15:44:14

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:34:03
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:44:14

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:34:03
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Sep 2020 15:44:14

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:34:03
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:44:14

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:34:03
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Sep 2020 15:44:14

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:34:03
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:44:14

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:36
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Un-verified.	(b) (4)	
	Isaac Perez (b) (4)	30 Mar 2021 19:21:02
User entered 'UN UNK 2015' reason for change:	(b) (4)	
Data Entry Error	Isaac Perez (b) (4)	30 Mar 2021 19:21:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Feb 2021 19:34:03
User entered '1 UNK 2015'	(b) (4), (b) (6)	10 Sep 2020 15:44:14

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:34:03
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:44:14

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:34:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 15:44:14

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:34:03
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:44:14

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:34:03
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 15:44:14

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 15:44:14

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 15:44:14

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 15:44:14

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS, PRODUCT: CALCIUM;VITAMIN D NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 09:42:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 09:42:55
Data point term sent to Coder User entered 'Calcium- Vitamin D'	System (b) (4), (b) (6)	10 Sep 2020 15:46:54 10 Sep 2020 15:46:05

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:53
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 15:46:05

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:53
User entered 'General Health'	(b) (4), (b) (6)	10 Sep 2020 15:46:05

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:53
User entered '600-500'	(b) (4), (b) (6)	10 Sep 2020 15:46:05

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:53
User entered 'IU (IU)'	(b) (4), (b) (6)	10 Sep 2020 15:46:05

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:53
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:46:05

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:53
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Sep 2020 15:46:05

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:53
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:46:05

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Sep 2020 15:46:05

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:53
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:46:05

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:53
User entered '27 Aug 2014'	(b) (4), (b) (6)	10 Sep 2020 15:46:05

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:53
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:46:05

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 15:46:05

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:53
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:46:05

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:53
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 15:46:05

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 15:46:05

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 15:46:05

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 15:46:05

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:55
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:48:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:48:47
Data point term sent to Coder	System	10 Sep 2020 15:47:55
User entered 'Vitamin B12'	(b) (4), (b) (6)	10 Sep 2020 15:47:07

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:36
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:34:21
User closed query 'Per DM CLR: Please review response as vitamins are considered as prophylaxis. Update as appropriate. (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 06:02:48
Query 'Per DM CLR: Please review response as vitamins are considered as prophylaxis. Update as appropriate. answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 13:47:36
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 13:47:18
Signature has been broken.	(b) (4), (b) (6)	06 Apr 2021 13:47:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 13:47:18
User opened query 'Per DM CLR: Please review response as vitamins are considered as prophylaxis. Update as appropriate. (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 09:30:07
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 19:37:55
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 15:47:07

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:55
User entered 'General Health'	(b) (4), (b) (6)	10 Sep 2020 15:47:07

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:55
User entered '1000'	(b) (4), (b) (6)	10 Sep 2020 15:47:07

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:36
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Un-verified.	(b) (4)	
	Isaac Perez (b) (4)	30 Mar 2021 19:22:09
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4)	
	Isaac Perez (b) (4)	30 Mar 2021 19:22:09
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 19:37:55
User entered 'Other (OTHER)'	(b) (4), (b) (6)	10 Sep 2020 15:47:07

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:36
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Un-verified.	(b) (4)	
	Isaac Perez (b) (4)	30 Mar 2021 19:22:09
User entered empty; reason for change Data Entry Error	(b) (4)	
	Isaac Perez (b) (4)	30 Mar 2021 19:22:09
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 19:37:55
User entered 'mcg'	(b) (4), (b) (6)	10 Sep 2020 15:47:07

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:55
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Sep 2020 15:47:07

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:55
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:47:07

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:55
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Sep 2020 15:47:07

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:55
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:47:07

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:55
User entered '17 Jul 2013'	(b) (4), (b) (6)	10 Sep 2020 15:47:07

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:55
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:47:07

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 15:47:07

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:55
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:47:07

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:55
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 15:47:07

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 15:47:07

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 15:47:07

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 15:47:07

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:57
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)	10 Sep 2020 15:48:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:48:47
Data point term sent to Coder User entered 'Aspirin'	System (b) (4), (b) (6)	10 Sep 2020 15:47:55 10 Sep 2020 15:47:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:57
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 15:47:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:57
User entered 'General Health'	(b) (4), (b) (6)	10 Sep 2020 15:47:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:57
User entered '81'	(b) (4), (b) (6)	10 Sep 2020 15:47:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:57
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Sep 2020 15:47:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:57
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:47:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:57
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Sep 2020 15:47:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:57
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:47:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:57
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Sep 2020 15:47:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:57
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:47:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:57
User entered '31 Aug 2010'	(b) (4), (b) (6)	10 Sep 2020 15:47:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:57
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:47:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 15:47:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:57
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:47:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:57
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 15:47:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 15:47:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 15:47:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 15:47:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:59
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE HYCLATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:49:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:49:38
Data point term sent to Coder	System	10 Sep 2020 15:48:57
User entered 'Doxycycline Hyclate'	(b) (4), (b) (6)	10 Sep 2020 15:48:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:59
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 15:48:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:59
User entered 'Rosacea'	(b) (4), (b) (6)	10 Sep 2020 15:48:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:59
User entered '100'	(b) (4), (b) (6)	10 Sep 2020 15:48:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:59
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Sep 2020 15:48:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:59
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:48:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:59
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Sep 2020 15:48:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:59
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:48:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:59
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Sep 2020 15:48:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:59
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:48:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:36
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Un-verified.	(b) (4)	
	Isaac Perez (b) (4)	30 Mar 2021 19:22:55
User entered 'UN UNK 2000' reason for change:	(b) (4)	
Data Entry Error	Isaac Perez (b) (4)	30 Mar 2021 19:22:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Feb 2021 19:37:59
User entered '1 UNK 2000'	(b) (4), (b) (6)	10 Sep 2020 15:48:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:59
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:48:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 15:48:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:59
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:48:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:37:59
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 15:48:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 15:48:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 15:48:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 15:48:40

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:34
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:38:04
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Jan 2021 18:37:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Jan 2021 18:37:42
Data point term sent to Coder	System	08 Jan 2021 18:36:41
Coding entries removed.	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:35:44
Coding entries removed.	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:35:44
User entered 'PLAvix' reason for change: New Information	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:35:44
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 21:47:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 21:47:31
Data point term sent to Coder	System	01 Jan 2021 18:31:21
User entered 'plaxis'	Catherine Abrams (b) (4) (b) (4)	01 Jan 2021 18:30:42

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:34
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:38:04
User entered 'No (N)'	Catherine Abrams (b) (4)	01 Jan 2021 18:30:42
	(b) (4)	

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:34
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:38:04
User entered 'transient ischemic attack'	Catherine Abrams (b) (4)	01 Jan 2021 18:30:42
	(b) (4)	

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:34
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:38:04
User entered '300' reason for change: New Information	Catherine Abrams (b) (4)	08 Jan 2021 18:35:44
User entered 'unknown'	(b) (4) Catherine Abrams (b) (4)	01 Jan 2021 18:30:42
	(b) (4)	

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:34
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:38:04
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 18:35:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Jan 2021 18:35:44
User entered 'mg (mg)' reason for change: New Information	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:35:44
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Jan 2021 18:30:42
User entered empty.	Catherine Abrams (b) (4) (b) (4)	01 Jan 2021 18:30:42

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:34
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:38:04
User entered empty.	Catherine Abrams (b) (4)	01 Jan 2021 18:30:42
	(b) (4)	

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:34
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:38:04
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 18:35:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Jan 2021 18:35:44
User entered 'once (ONCE)' reason for change: New Information	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:35:44
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Jan 2021 18:30:42
User entered empty.	Catherine Abrams (b) (4) (b) (4)	01 Jan 2021 18:30:42

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:34
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:38:04
User entered empty.	Catherine Abrams (b) (4)	01 Jan 2021 18:30:42
	(b) (4)	

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:34
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:38:04
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 18:35:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Jan 2021 18:35:44
User entered 'Oral (ORAL)' reason for change: New Information	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:35:44
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Jan 2021 18:30:42
User entered empty.	Catherine Abrams (b) (4) (b) (4)	01 Jan 2021 18:30:42

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:34
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:38:04
User entered empty.	Catherine Abrams (b) (4)	01 Jan 2021 18:30:42
	(b) (4)	

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:34
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:38:04
User entered '31 Dec 2020'	Catherine Abrams (b) (4)	01 Jan 2021 18:30:42
	(b) (4)	

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:34
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:38:04
User entered '0'	Catherine Abrams (b) (4)	01 Jan 2021 18:30:42
	(b) (4)	

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:34
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:38:04
User entered 'No (N)' reason for change: New Information	Catherine Abrams (b) (4)	08 Jan 2021 18:35:44
User entered 'Yes (Y)'	(b) (4) Catherine Abrams (b) (4)	01 Jan 2021 18:30:42
	(b) (4)	

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:34
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:38:04
User entered '31 Dec 2020' reason for change: New Information	Catherine Abrams (b) (4)	08 Jan 2021 18:35:44
User entered empty.	(b) (4) Catherine Abrams (b) (4)	01 Jan 2021 18:30:42
	(b) (4)	

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:34
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:38:04
User entered 'No (N)'	Catherine Abrams (b) (4)	01 Jan 2021 18:30:42
	(b) (4)	

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:34
User entered empty.	System	01 Jan 2021 18:30:42

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:34
User entered empty.	System	01 Jan 2021 18:30:42

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:34
User entered empty.	System	01 Jan 2021 18:30:42

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:42:17
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Jan 2021 18:38:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Jan 2021 18:38:43
Data point term sent to Coder	System	08 Jan 2021 18:36:42
User entered 'Plavix'	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:36:36

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:42:17
User entered 'No (N)'	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:36:36

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:42:17
User entered 'TIA'	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:36:36

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:42:17
User entered '75'	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:36:36

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:42:17
User entered 'mg (mg)'	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:36:36

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:42:17
User entered empty.	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:36:36

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:42:17
User entered 'once daily (QD)'	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:36:36

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:42:17
User entered empty.	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:36:36

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:42:17
User entered 'Oral (ORAL)'	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:36:36

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:42:17
User entered empty.	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:36:36

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:42:17
User entered '3 Jan 2021'	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:36:36

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:42:17
User entered '0'	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:36:36

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Feb 2021 03:28:49
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with ' Medication still ongoing as per 2/15/21 for post TIA recovery.' (Site from DM).	Isaac Perez (b) (4) (b) (4)	15 Feb 2021 15:26:24
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 19:42:17
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 13:03:18
User entered 'Yes (Y)'	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:36:36

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:42:17
User entered empty.	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:36:36

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:42:17
User entered 'No (N)'	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:36:36

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 18:36:36

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 18:36:36

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Jan 2021 18:36:36

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:39

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:42:19
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Jan 2021 18:41:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Jan 2021 18:41:41
Data point term sent to Coder	System	08 Jan 2021 18:40:46
User entered 'lipitor'	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:39:49

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:42:19
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 18:40:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Jan 2021 18:40:00
User entered 'No (N)' reason for change: New Information	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:40:00
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 18:39:49
User entered empty.	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:39:49

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:42:19
User entered 'high cholesterol'	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:39:49

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:42:19
User entered '40' reason for change: New Information	Catherine Abrams (b) (4)	13 Jan 2021 15:16:21
User entered 'unknown'	(b) (4) Catherine Abrams (b) (4)	08 Jan 2021 18:39:49
	(b) (4)	

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:42:19
User entered 'mg (mg)' reason for change: New Information	Catherine Abrams (b) (4) (b) (4)	13 Jan 2021 15:16:21
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 17:50:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Jan 2021 17:50:10
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 17:50:10
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 18:39:49
User entered empty.	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:39:49

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:42:19
User entered empty; reason for change New Information	Catherine Abrams (b) (4) (b) (4)	13 Jan 2021 15:16:21
User entered 'Unknown' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 17:50:10
User entered empty.	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:39:49

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:42:19
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 15:16:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Jan 2021 15:16:21
User entered 'once daily (QD)' reason for change: Data Entry Error	Catherine Abrams (b) (4) (b) (4)	13 Jan 2021 15:16:21
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 18:39:49
User entered empty.	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:39:49

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:42:19
User entered empty.	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:39:49

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:42:19
User entered 'Oral (ORAL)'	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:39:49

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:42:19
User entered empty.	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:39:49

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HIGH CHOLESTEROL should be recorded, and update con med indication or provide clarification. (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 03:29:39
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HIGH CHOLESTEROL should be recorded, and update con med indication or provide clarification. answered with 'Medication was added due to TIA diagnosis.' (Site from DM).	Isaac Perez (b) (4)	15 Feb 2021 15:27:06
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 19:42:19
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HIGH CHOLESTEROL should be recorded, and update con med indication or provide clarification. (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 13:05:02
User entered '3 Jan 2021'	Catherine Abrams (b) (4)	08 Jan 2021 18:39:49

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:42:19
User entered '0'	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:39:49

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:42:19
User entered 'Yes (Y)'	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:39:49

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:42:19
User entered empty.	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:39:49

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:42:19
User entered 'No (N)'	Catherine Abrams (b) (4) (b) (4)	08 Jan 2021 18:39:49

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Jan 2021 15:16:21
User entered empty.	System	08 Jan 2021 18:39:49

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Jan 2021 15:16:21
User entered empty.	System	08 Jan 2021 18:39:49

US3632064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Jan 2021 15:16:21
User entered empty.	System	08 Jan 2021 18:39:49

US3632064

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:14:39

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:04:17
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:28:30
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4), (b) (6)	05 Mar 2021 18:56:11
DataPoint Un-verified.	Isaac Perez (b) (4)	15 Feb 2021 14:16:14
User entered 'No (N)' reason for change: Per Query Resolution	Isaac Perez (b) (4)	15 Feb 2021 14:16:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:47:24
User entered 'Yes (Y)'	Catherine Abrams (b) (4)	01 Jan 2021 18:30:55

US3632064

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:14:39

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:29:25
User entered '03 Jan 2021'	(b) (4), (b) (6)	05 Mar 2021 19:03:25

US3632064

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:14:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:29:25
User entered 'MRI'	(b) (4), (b) (6)	05 Mar 2021 19:03:25

US3632064

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:14:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:29:25
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	05 Mar 2021 19:03:25

US3632064

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:14:39

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:29:25
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 19:03:25

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'USA-US120-2021-MRNA-1273-P301000001'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'Yes (Y)'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'No (N)'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'Yes (Y)'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'Yes (Y)'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'No (N)'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'No (N)'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'No (N)'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'Colleen'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'Kelley'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'GA'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 22:26:42
User entered 'US'	System	04 Jan 2021 19:37:17

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	16 Feb 2021 19:11:39
User entered '3'	System	05 Feb 2021 17:49:22
User entered '2'	System	13 Jan 2021 22:26:38
User entered '1'	System	04 Jan 2021 19:37:17

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'USA-US120-2021-MRNA-1273-P301000001'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'Yes (Y)'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

Death

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'No (N)'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'Yes (Y)'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'Yes (Y)'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'No (N)'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'No (N)'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'No (N)'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'Colleen'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'Kelley'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'GA'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 22:26:42
User entered 'US'	System	04 Jan 2021 19:37:17

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	16 Feb 2021 19:11:39
User entered '3'	System	05 Feb 2021 17:49:22
User entered '2'	System	13 Jan 2021 22:26:38
User entered '1'	System	04 Jan 2021 19:37:17

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:14:39

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:08:14
User entered '04/Jan/2021 19:37'	System	04 Jan 2021 19:37:17

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:14:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 22:26:42
User entered 'I'	(b) (4), (b) (6)	04 Jan 2021 19:37:17

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'USA-US120-2021-MRNA-1273-P301000001'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'Yes (Y)'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'No (N)'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'Yes (Y)'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'Yes (Y)'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'No (N)'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'No (N)'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'No (N)'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'Colleen'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'Kelley'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'GA'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 22:26:42
User entered 'US'	System	04 Jan 2021 19:37:17

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	16 Feb 2021 19:11:39
User entered '3'	System	05 Feb 2021 17:49:22
User entered '2'	System	13 Jan 2021 22:26:38
User entered '1'	System	04 Jan 2021 19:37:17

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:14:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:08:14
User entered '13/Jan/2021 17:26'	System	13 Jan 2021 22:26:38

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:14:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 22:26:42
User entered 'l'	(b) (4), (b) (6)	13 Jan 2021 22:26:38

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'USA-US120-2021-MRNA-1273-P301000001'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'Yes (Y)'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

Death

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'No (N)'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'Yes (Y)'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'Yes (Y)'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'No (N)'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'No (N)'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'No (N)'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'Colleen'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'Kelley'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'GA'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 22:26:42
User entered 'US'	System	04 Jan 2021 19:37:17

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	16 Feb 2021 19:11:39
User entered '3'	System	05 Feb 2021 17:49:22
User entered '2'	System	13 Jan 2021 22:26:38
User entered '1'	System	04 Jan 2021 19:37:17

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:14:39

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:30:49
User entered '05/Feb/2021 17:49'	System	05 Feb 2021 17:49:22

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:14:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:30:49
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 19:11:24
User entered '1'	(b) (4), (b) (6)	05 Feb 2021 17:49:22

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'USA-US120-2021-MRNA-1273-P301000001'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'Yes (Y)'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'No (N)'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'Yes (Y)'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'Yes (Y)'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'No (N)'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'No (N)'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'No (N)'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'Colleen'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'Kelley'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:37:12
User entered 'GA'	System	04 Jan 2021 19:36:42

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:49:12
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 17:49:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:08:14
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 22:26:42
User entered 'US'	System	04 Jan 2021 19:37:17

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	16 Feb 2021 19:11:39
User entered '3'	System	05 Feb 2021 17:49:22
User entered '2'	System	13 Jan 2021 22:26:38
User entered '1'	System	04 Jan 2021 19:37:17

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:14:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:30:51
User entered '16/Feb/2021 13:11'	System	16 Feb 2021 19:11:39

US3632064

Folder: SAE USA-US120-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:14:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:11:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:30:51
User entered 'I'	(b) (4), (b) (6)	16 Feb 2021 19:11:39