

US3602004 (Prod: Hackensack University Medical Center)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:08:05

All time stamps listed in this document are displayed in GMT

US3602004

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 22:06:19

Generated On: 10 Jun 2021 09:08:05

[Participant ID](#)

US3602004

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

US3602004

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 20:54:56

Generated On: 10 Jun 2021 09:08:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 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

US3602004

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 20:54:55

Generated On: 10 Jun 2021 09:08:05

Date of Birth (MMM yyyy)	(b) (6) 1963
Age	57
Age Units	YEARS
Age (Derived)	57
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3602004

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 20:54:55

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 20:54:55

Generated On: 10 Jun 2021 09:08:05

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3602004

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 20:54:56

Generated On: 10 Jun 2021 09:08:05

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 20:54:55

Generated On: 10 Jun 2021 09:08:05

Condition	DIABETES
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3602004

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 20:54:55

Generated On: 10 Jun 2021 09:08:05

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 20:54:55

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 20:54:55

Generated On: 10 Jun 2021 09:08:05

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 20:54:55

Generated On: 10 Jun 2021 09:08:05

Condition	VASOVAGAL EPISODE
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2011
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	JAN 2011
Stop Year (derived)	2011

US3602004

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 20:54:55

Generated On: 10 Jun 2021 09:08:05

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 20:54:55

Generated On: 10 Jun 2021 09:08:05

Condition	IRRITABLE BOWEL SYNDROME
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Feb 2021 20:54:55

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Feb 2021 20:54:55

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 15 Feb 2021 20:54:55

Generated On: 10 Jun 2021 09:08:05

Condition	INSOMNIA (SELF-DIAGNOSED)
Start date (dd MMM yyyy)	UN JUL 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)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3602004

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 15 Feb 2021 20:54:55

Generated On: 10 Jun 2021 09:08:05

Condition	GASTROESOPHAGEAL REFLUX DISORDER (GERD) (SELF-DIAGNOSED)
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

US3602004

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 15 Feb 2021 20:54:55

Generated On: 10 Jun 2021 09:08:05

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3602004

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 20:54:56

Generated On: 10 Jun 2021 09:08:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	2 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	11:00 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 11:00
Height (<i>xxx.x</i>)	63 in
Weight (<i>xxx.x</i>)	160 lb
BMI (<i>xxx.x</i>)	28.40199 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)	

US3602004

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 20:54:56

Generated On: 10 Jun 2021 09:08:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 20:54:55

Generated On: 10 Jun 2021 09:08:05

Date of assessment (dd MMM yyyy) 2 SEP 2020

Is the participant of childbearing potential? Yes ☐
No ☒

If No, what is the reason? Surgically sterile ☐
Post-menopausal ☒
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 2012

Date of last menstruation unknown False

US3602004

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 20:54:56

Generated On: 10 Jun 2021 09:08:05

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 20:54:56

Generated On: 10 Jun 2021 09:08:05

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 20:38:49

Generated On: 10 Jun 2021 09:08:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3602004

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 20:38:49

Generated On: 10 Jun 2021 09:08:05

What was the date of randomization? (dd MMM yyyy) 02 SEP 2020

What was the participant's randomization number? 145584

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 ☒

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 20:38:49

Generated On: 10 Jun 2021 09:08:05

Height	ND - Not Done
Weight	ND - Not Done

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 20:38:49

Generated On: 10 Jun 2021 09:08:05

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 SEP 2020
Time of assessment (00:00-23:59)	11:45 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 11:45
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	19 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 20:38:49

Generated On: 10 Jun 2021 09:08:05

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 SEP 2020
Time of assessment (00:00-23:59)	13:55 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 13:55
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3602004

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 20:38:49

Generated On: 10 Jun 2021 09:08:05

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3602004

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 20:38:49

Generated On: 10 Jun 2021 09:08:05

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 2 SEP 2020

What was the treatment time? (00:00-23:59) 13:25 (24 HR)

Treatment Date and Time (derived) 2 SEP 2020 13:25

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

What was the frequency of the study treatment dosing? ONCE

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

US3602004

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 20:38:49

Generated On: 10 Jun 2021 09:08:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 SEP 2020
Collection time (00:00-23:59)	12:30 (24 HR)
Collection date and time (derived)	2 SEP 2020 12:30

US3602004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 20:38:49

Generated On: 10 Jun 2021 09:08:05

Collection date (dd MMM yyyy)			2 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:30	2 SEP 2020 12:30
Nasopharyngeal Swab 2	No		

US3602004

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:38:49

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 14:26

PC Open Date & Time

02 SEP 2020 13:45

PC Close Date & Time

02 SEP 2020 16:15

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.2 °F

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

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

PC Time Stamp	02 SEP 2020 21:03
PC Open Date & Time	02 SEP 2020 17:10
PC Close Date & Time	03 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	03 SEP 2020 14:26
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <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 checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	04 SEP 2020 13:01
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 20:00

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 21:19

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

07 SEP 2020 20:26

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 21:58

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 14:27

PC Open Date & Time

02 SEP 2020 13:45

PC Close Date & Time

02 SEP 2020 16:15

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 21:04

PC Open Date & Time

02 SEP 2020 17:10

PC Close Date & Time

03 SEP 2020 11:59

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 14:26

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 13:00

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 20:01

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 21:21

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 20:27

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 21:58

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 14:27
PC Open Date & Time	02 SEP 2020 13:45
PC Close Date & Time	02 SEP 2020 16:15

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 21:05
PC Open Date & Time	02 SEP 2020 17:10
PC Close Date & Time	03 SEP 2020 11:59

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 14:27
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 13:02
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

58 of 2600

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 20:01
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

60 of 2600

EAB) (1725)

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 21:25
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 20:28
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 21:59
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3602004

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:54:55

Generated On: 10 Jun 2021 09:08:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3602004

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:54:55

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602004

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 20:56:01

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:54:55

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602004

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:54:55

Generated On: 10 Jun 2021 09:08:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3602004

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:54:55

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602004

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 20:38:49

Generated On: 10 Jun 2021 09:08:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3602004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 20:38:49

Generated On: 10 Jun 2021 09:08:05

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	11:13 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 11:13
Temperature (xxx.x)	96.4 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3602004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 20:38:49

Generated On: 10 Jun 2021 09:08:05

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	13:13 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 13:13
Temperature (xxx.x)	96.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3602004

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 20:38:49

Generated On: 10 Jun 2021 09:08:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3602004

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 20:38:49

Generated On: 10 Jun 2021 09:08:05

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 28 SEP 2020

What was the treatment time? (00:00-23:59) 12:41 (24 HR)

Treatment Date and Time (derived) 28 SEP 2020 12:41

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

US3602004

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 20:38:49

Generated On: 10 Jun 2021 09:08:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 SEP 2020
Collection time (00:00-23:59)	11:34 (24 HR)
Collection date and time (derived)	28 SEP 2020 11:34

US3602004

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 20:38:49

Generated On: 10 Jun 2021 09:08:05

Collection date (dd MMM yyyy)			28 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:34	28 SEP 2020 11:34
Nasopharyngeal Swab 2	No		

US3602004

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:38:49

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 13:14

PC Open Date & Time

28 SEP 2020 13:01

PC Close Date & Time

28 SEP 2020 15:31

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.4 °F

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

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

PC Time Stamp	28 SEP 2020 20:16
PC Open Date & Time	28 SEP 2020 16:26
PC Close Date & Time	29 SEP 2020 11:59

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	29 SEP 2020 18:54
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 21:16

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 20:07

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

02 OCT 2020 22:50

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 6

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

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

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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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 20:09

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

04 OCT 2020 18:51

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 8

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 21:28

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 13:14

PC Open Date & Time

28 SEP 2020 13:01

PC Close Date & Time

28 SEP 2020 15:31

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 20:17

PC Open Date & Time

28 SEP 2020 16:26

PC Close Date & Time

29 SEP 2020 11:59

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

3

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

4

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 19:00

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

9

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

3

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 21:21

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 20:09

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 22:51

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 20:10

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 18:53

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

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

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 13:15
PC Open Date & Time	28 SEP 2020 13:01
PC Close Date & Time	28 SEP 2020 15:31

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

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

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 20:18
PC Open Date & Time	28 SEP 2020 16:26
PC Close Date & Time	29 SEP 2020 11:59

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 19:01
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 21:24
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 20:09
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 22:51
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 20:11
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 18:54
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3602004

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	05 OCT 2020 21:26
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3602004

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 20:56:01

Generated On: 10 Jun 2021 09:08:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3602004

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:54:55

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602004

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 20:56:01

Generated On: 10 Jun 2021 09:08:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3602004

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:54:55

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602004

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:54:55

Generated On: 10 Jun 2021 09:08:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3602004

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:54:55

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602004

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 20:38:49

Generated On: 10 Jun 2021 09:08:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3602004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 20:38:49

Generated On: 10 Jun 2021 09:08:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 OCT 2020
Time of assessment (00:00-23:59)	13:55 (24 HR)
Vital Signs Date and Time (derived)	26 OCT 2020 13:55
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3602004

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 20:38:49

Generated On: 10 Jun 2021 09:08:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 OCT 2020

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

US3602004

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 20:38:49

Generated On: 10 Jun 2021 09:08:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 OCT 2020
Collection time (00:00-23:59)	13:55 (24 HR)
Collection date and time (derived)	26 OCT 2020 13:55

US3602004

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:38:49

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 NOV 2020 19:31:22
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3602004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

09 NOV 2020 21:29:34

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3602004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	16 NOV 2020 20:36:58
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 NOV 2020 18:07:15
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 NOV 2020 17:57:07

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 type="radio"/> Yes <input checked="" 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)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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	06 DEC 2020 13:39:42
Patient Cloud Open Date & Time	04 DEC 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
130 of 2600	

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

08 DEC 2020 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 DEC 2020 20:31:06

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 DEC 2020 18:06:21

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 14:16:10

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 JAN 2021 22:11:28

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 JAN 2021 19:11:46

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 JAN 2021 06:58:48

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 JAN 2021 18:51:43

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 JAN 2021 07:16:40

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 FEB 2021 18:54:13

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 FEB 2021 17:05:01
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 16:17:10

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAR 2021 18:23:46

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 17:34:24

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 MAR 2021 20:06:42
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 MAR 2021 18:11:58

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 MAR 2021 06:38:54

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 APR 2021 17:06:07

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 08:02:55

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 APR 2021 17:31:37

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 17:18:08

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 13:36:23

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 271

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

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

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

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

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

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

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

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 JUL 2021 00:01
Patient Cloud Close Date & Time	27 JUL 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Patient Cloud Open Date & Time	13 AUG 2021 00:01
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Patient Cloud Close Date & Time	17 AUG 2021 23:59
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US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Patient Cloud Open Date & Time	12 NOV 2021 00:01
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Patient Cloud Close Date & Time	16 NOV 2021 23:59
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US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 NOV 2021 00:01
Patient Cloud Close Date & Time	23 NOV 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 572

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Patient Cloud Open Date & Time	25 MAR 2022 00:01
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Patient Cloud Close Date & Time	29 MAR 2022 23:59
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US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 579
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 607

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

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

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

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

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

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

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

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 663
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 SEP 2022 00:01
Patient Cloud Close Date & Time	27 SEP 2022 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

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

US3602004

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:08:05

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		01 MAR 2021 18:23:58

US3602004

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3602004

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602004

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 20:56:01

Generated On: 10 Jun 2021 09:08:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3602004

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602004

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 3 FEB 2021

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

Comments SUBJECT WAS UNABLE TO
REACH STUDY PERSONEL TO
RETURN CALL FROM 1/28/21
If Contact Not Made, please provide Comments

US3602004

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602004

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 20:56:01

Generated On: 10 Jun 2021 09:08:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3602004

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 20:56:01

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602004

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 20:56:01

Generated On: 10 Jun 2021 09:08:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3602004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 20:56:01

Generated On: 10 Jun 2021 09:08:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 MAR 2021
Time of assessment (00:00-23:59)	08:39 (24 HR)
Vital Signs Date and Time (derived)	29 MAR 2021 08:39
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3602004

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 20:56:01

Generated On: 10 Jun 2021 09:08:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 MAR 2021

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

US3602004

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 20:56:01

Generated On: 10 Jun 2021 09:08:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 MAR 2021
Collection time (00:00-23:59)	08:50 (24 HR)
Collection date and time (derived)	29 MAR 2021 08:50

US3602004

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 20:56:01

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602004

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3602004

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 05 Apr 2021 20:56:01

Generated On: 10 Jun 2021 09:08:05

Date of Contact	06 DEC 2020
Time of Contact	08:15
Date and Time of Contact (derived)	06 DEC 2020 08:15
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	04 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
PRODUCTION RELEASE (v12.003		329 of 2600
EAB) (1725)		

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

330 of 2600

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	05 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	06 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	07 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	08 DEC 2020	
Assessment Not Done	False	
O2 Saturation	91 %	
O2 Saturation Units	%	
Temperature	99.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	09 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	96 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.7 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	10 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.4 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 19 Feb 2021 22:06:19

Generated On: 10 Jun 2021 09:08:05

Date of Visit 7 DEC 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒
No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☐
No ☒

Date of Test 7 DEC 2020

Type of Test Performed Nasopharyngeal Swab ☒
Nasal Swab ☐
Saliva Test ☐
Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐
No ☒

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified? Yes ☐
No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3602004

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	9 DEC 2020
Day 5	Yes	11 DEC 2020
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3602004

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3602004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 20:56:01

Generated On: 10 Jun 2021 09:08:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	7 DEC 2020
Time of assessment (<i>00:00-23:59</i>)	09:33 (24 HR)
Vital Signs Date and Time (derived)	7 DEC 2020 09:33
Height (<i>xxx.x</i>)	ND - Not Done
Weight (<i>xxx.x</i>)	ND - Not Done
Temperature (<i>xxx.x</i>)	97.4 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	70 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	160 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3602004

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 DEC 2020

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

US3602004

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

7 DEC 2020

US3602004

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

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

Visit date (dd MMM yyyy)	08 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
------------	---------------

US3602004

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 20:56:01

Generated On: 10 Jun 2021 09:08:05

Date of updated informed consent (dd MMM yyyy) 08 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 08 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3602004

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	08 JAN 2021
Collection time (00:00-23:59)	11:32 (24 HR)
Collection date and time (derived)	08 JAN 2021 11:32

US3602004

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 22:06:20

Generated On: 10 Jun 2021 09:08:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	08 JAN 2021
Collection time (00:00 - 23:59)	11:30
Collection Date and Time (derived)	08 JAN 2021 11:30

US3602004

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 22:06:19

Generated On: 10 Jun 2021 09:08:05

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 13 Mar 2021 23:39:01

Generated On: 10 Jun 2021 09:08:05

AEID

Adverse event

RIGHT SINUS CONGESTION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

04 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)

11 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 13 Mar 2021 23:39:01

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 13 Mar 2021 23:39:01

Generated On: 10 Jun 2021 09:08:05

AEID

Adverse event

INTERMITTENT CHEST
TIGHTNESS

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)

8 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)

08 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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EAB) (1725)

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 13 Mar 2021 23:39:01

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 13 Mar 2021 23:39:01

Generated On: 10 Jun 2021 09:08:05

AEID	USA-US079-2021-MRNA-1273-P30 1000003
Adverse event	NSTEMI (NON-ST SEGMENT ELEVATION MYOCARDIAL INFARCTION)
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	3 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	4 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	3 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	4 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 13 Mar 2021 23:39:01

Generated On: 10 Jun 2021 09:08:05

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

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 13 Mar 2021 23:39:01

Generated On: 10 Jun 2021 09:08:05

ON 3/JAN 2021 AT 2300 UPON
STANDING UP SHE REPORTS
THAT SHE BEGAN TO
EXPERIENCE CHEST PRESSURE,
WHICH SHE DESCRIBED AS " A
HEAVINESS, LIKE SOMEONE
WAS SITTING ON MY CHEST".
SHE CALLED 911. SHE WAS
TRANSPORTED TO LOCAL ER
VIA AMBULANCE. SHE WAS
GIVEN ASPIRIN,
NITROGLYCERIN, AND
LOPRESSOR, IN THE ER. SHE
REPORTS THAT CHEST
PRESSURE AND SHORTNESS
BEGAN TO RESOLVE UPON
TAKING NITROGLYCERIN. SHE
REPORTS THAT ALL THE
CHEST DISCOMFORT AND
SHORTNESS OF BREATH
COMPLETELY RESOLVED BY
0300 ON 4/JAN/2021. THE EKG
REVEALED A NSTEMI. HER
TROPONIN'S WERE GROSSLY
POSITIVE. UPON THE RETURN
OF POSITIVE TROPONIN SHE
WAS TRANSPORTED TO CATH
LAB WHERE CARDIAC
CATHETERIZATION WAS
PERFORMED. SHE DID NOT
REQUIRE STENTS- SHE
REPORTS THAT THE CARDIAC
CATHETERIZATION REVELED
MINOR PLAQUES BUT "NO
BLOCKAGE". SHE IS SCHEDULE

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 13 Mar 2021 23:39:01

Generated On: 10 Jun 2021 09:08:05

FOR FOLLOW UP
APPOINTMENT WITH
CARDIOLOGIST 12/JAN/2021.
UPON DISCHARGE FROM THE
HOSPITAL AT 1500 ON
4/JAN/2021 SHE WAS
PRESCRIBED 81MG OF ASPIRIN
DAILY. AT THE TIME OF
TELEPHONE CONTACT SHE
REPORTS THAT SHE IS
ASYMPTOMATIC. PI MADE
AWARE OF MAAE.
COVID-19 TESTING WAS NOT
PERFORMED AT HOSPITAL.

TROPONIN LEVELS WERE AS
FOLLOWS: ON JAN 04 07:42:
TROPONIN-L 0.17NG/ML HIGH;
ON JAN 04 09:42: TROPONIN-L
0.16NG/ML HIGH. THE NORMAL
TROPONIN REFERENCE RANGE
IS 0.00 TO 0.04 NG/ML.

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

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 13 Mar 2021 23:39:01

Generated On: 10 Jun 2021 09:08:05

AEID

Adverse event

UPPER RESPIRATORY TRACT
INFECTION

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)

4 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)

10 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 13 Mar 2021 23:39:01

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

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 13 Mar 2021 23:39:01

Generated On: 10 Jun 2021 09:08:05

AEID

Adverse event

SHORTNESS OF BREATH

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)

3 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

4 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

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 13 Mar 2021 23:39:01

Generated On: 10 Jun 2021 09:08:05

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 22:06:19

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

Yes ☒

No ☐

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

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication RESTLESS LEG SYNDROME

Dose per administration 400

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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US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

	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) _____		
Start date completely unknown		True
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)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication IDDM

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

	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) _____		
Start date completely unknown		True
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)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

	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) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

Name of Medication JARDIANCE

Prophylaxis Yes ☐
No ☒

Indication IDDM

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

	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) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

Name of Medication LORATADINE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

	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) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication ORAL PAIN

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

	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	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

Name of Medication DOTERRA OIL

Prophylaxis Yes ☐
No ☒

Indication ANTI-REFLUX (FOR
SELF-DIAGNOSED GERD)

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

	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) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

Name of Medication HEMP EXTRACT

Prophylaxis Yes ☐
No ☒

Indication SLEEP AIDE (FOR
SELF-DIAGNOSED INSOMNIA)

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

	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 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

Name of Medication BERBERINE

Prophylaxis Yes ☐
No ☒

Indication GLYCEMIC CONTROL

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

	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) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication PAIN AT INJECTION SITE

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

FOR THIS ONE EVENT

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

	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 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 7 SEP 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication HEADACHE AND CONGESTION

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

	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)		04 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

Name of Medication SUDAFED OTC
(PSEUDOEPHEDRINE HCL)

Prophylaxis Yes ☐
No ☒

Indication UPPER RESPIRATORY TRACT
INFECTION

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

	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)		10 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

Name of Medication FLONASE (FLUTICASONE)

Prophylaxis Yes ☐
No ☒

Indication UPPER RESPIRATORY TRACT
INFECTION

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" 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)	10 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

Name of Medication ASA (ASPIRIN)

Prophylaxis Yes ☒
No ☐

Indication NSTEMI (NON-ST SEGMENT
ELEVATED MYOCARDIAL
INFARCTION)

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

	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)		4 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

Name of Medication NITROGLYCERIN (NITROSTAT)
TABLET

Prophylaxis Yes ☐
No ☒

Indication NSTEMI (NON-ST SEGMENT
ELEVATION MYOCARDIAL
INFARCTION)

Dose per administration UNK

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

	Transdermal	<input type="radio"/>
	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 checked="" type="radio"/>
If route of administration is Other, specify	SUBLINGUAL	
Start date (dd MMM yyyy)	4 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	4 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

Name of Medication LOPRESSOR (METOPROLOL
TARTRATE)

Prophylaxis Yes ☐
No ☒

Indication NSTEMI (NON-ST SEGMENT
ELEVATION MYOCARDIAL
INFARCTION)

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

	Transdermal	<input type="checkbox"/>
	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 checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	4 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	4 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication SHORTNESS OF BREATH

Dose per administration 180

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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Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" 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)	3 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy) 3 JAN 2021		
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

US3602004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3602004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 05 Apr 2021 20:56:00

Generated On: 10 Jun 2021 09:08:05

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
4 JAN 2021	EKG	Adverse Event	
4 JAN 2021	LEFT HEART CATHETERIZATION	Adverse Event	
4 JAN 2021	BLOOD WORK-UP	Diagnostic	

US3602004

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:08:05

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3602004

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:08:05

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 05 Apr 2021 20:56:01

Generated On: 10 Jun 2021 09:08:05

SAEID	USA-US079-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BINDU
Investigator's Last Name	BALANI
Site Address: Street	
Site Address: City	
Site Address: State	NJ
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 05 Apr 2021 20:56:01

Generated On: 10 Jun 2021 09:08:05

SAEID	USA-US079-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BINDU
Investigator's Last Name	BALANI
Site Address: Street	
Site Address: City	
Site Address: State	NJ
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	26/FEB/2021 10:19
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

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 05 Apr 2021 20:56:01

Generated On: 10 Jun 2021 09:08:05

SAEID	USA-US079-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BINDU
Investigator's Last Name	BALANI
Site Address: Street	
Site Address: City	
Site Address: State	NJ
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	04/MAR/2021 10:23
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

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 05 Apr 2021 20:56:01

Generated On: 10 Jun 2021 09:08:05

SAEID	USA-US079-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BINDU
Investigator's Last Name	BALANI
Site Address: Street	
Site Address: City	
Site Address: State	NJ
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	05/MAR/2021 09:27
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

US3602004 (Prod: Hackensack University Medical Center)

US3602004

Form: Participant Creation

Generated On: 10 Jun 2021 09:08:05

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'US3602004'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 16:05:46

US3602004

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:11:25

US3602004

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '02 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 16:05:47

US3602004

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:11:25

US3602004

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered 'SCRN'	System	02 Sep 2020 16:11:25

US3602004

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered (b) (6) 1963'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 16:05:48

US3602004

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:08:05

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '57'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:12:07

US3602004

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:08:05

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered 'YEARS'	System	02 Sep 2020 16:12:07

US3602004

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:08:05

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered '57'	System	02 Sep 2020 16:17:29

US3602004

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:08:05

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:12:07

US3602004

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:08:05

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:12:07

US3602004

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:08:05

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'I'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:12:07

US3602004

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:08:05

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:12:07

US3602004

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:08:05

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:12:07

US3602004

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:08:05

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:12:07

US3602004

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:08:05

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:12:07

US3602004

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:08:05

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:12:07

US3602004

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:08:05

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:12:07

US3602004

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:08:05

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:12:07

US3602004

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:08:05

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:12:07

US3602004

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '2 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:17:29

US3602004

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered 'Sep 2020'	System	02 Sep 2020 16:17:29

US3602004

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered '2020'	System	02 Sep 2020 16:17:29

US3602004

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:08:05

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:17:29

US3602004

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:17:29

US3602004

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:17:29

US3602004

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:08:05

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:17:29

US3602004

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:08:05

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:17:29

US3602004

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:08:05

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 16:05:47

US3602004

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:08:05

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered 'I'	System	02 Sep 2020 16:37:56

US3602004

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:37:56

US3602004

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:08:05

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Sep 2020 18:27:30
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 16:38:48

US3602004

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:08:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Diabetes mellitus, LLT: Diabetes - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 18:29:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 18:29:45
Data point term sent to Coder	System	15 Sep 2020 18:28:57
User entered 'Diabetes'	(b) (4), (b) (6)	15 Sep 2020 18:27:57

US3602004

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'UN UNK 2005'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 18:27:57

US3602004

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 18:27:57

US3602004

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:08:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 18:27:57

US3602004

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 18:27:57

US3602004

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:08:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 18:27:57

US3602004

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered 'Jan 2005'	System	15 Sep 2020 18:27:57

US3602004

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered '2005'	System	15 Sep 2020 18:27:57

US3602004

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered empty.	System	15 Sep 2020 18:27:57

US3602004

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered empty.	System	15 Sep 2020 18:27:57

US3602004

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:08:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:47:06
' (Site from DM).		
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	05 Nov 2020 16:48:07
' answered with 'This condition is not ongoing, most like the subject no longer takes medication for this as the problem has been resolved. ' (Site from DM).		
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	21 Oct 2020 13:33:13
' (Site from DM).		
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 12:59:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	24 Sep 2020 12:59:49
Data point term sent to Coder	System	24 Sep 2020 12:59:12
User closed query 'CDM-Coding: Please either provide a single clinical diagnosis for this reported event or split to report each event separately to capture coding for all terms. Example: 1) ASTHMA 2) COLD (Specify if its common cold or feeling cold) 3)BRONCHITIS	System	24 Sep 2020 12:58:26
' (Site from System).		

US3602004

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:08:05

[Condition](#)

Audit	User	Time (GMT)
Query 'CDM-Coding: Please either provide a single clinical diagnosis for this reported event or split to report each event separately to capture coding for all terms. Example: 1) ASTHMA 2) COLD (Specify if its common cold or feeling cold) 3)BRONCHITIS ' answered with 'updated.' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 12:58:26
User entered 'ASTHMA' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 12:58:19
User opened query 'CDM-Coding: Please either provide a single clinical diagnosis for this reported event or split to report each event separately to capture coding for all terms. Example: 1) ASTHMA 2) COLD (Specify if its common cold or feeling cold) 3)BRONCHITIS ' (Site from System).	Coder Import (b) (4) (b) (4)	21 Sep 2020 06:46:33
Data point term sent to Coder	System	16 Sep 2020 13:30:47
User entered 'Asthma/ Cold/ Bronchitis'	(b) (4), (b) (6)	16 Sep 2020 13:30:43

US3602004

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'UN UNK 1980' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:09:25
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 13:30:43

US3602004

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:09:25
User entered '1'	(b) (4), (b) (6)	16 Sep 2020 13:30:43

US3602004

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:08:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:30:43

US3602004

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'UN UNK 1980'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:30:43

US3602004

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:08:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:30:43

US3602004

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered 'Jan 1980'	System	28 Sep 2020 17:09:25
User entered empty.	System	16 Sep 2020 13:30:43

US3602004

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered '1980'	System	28 Sep 2020 17:09:25
User entered empty.	System	16 Sep 2020 13:30:43

US3602004

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered 'Jan 1980'	System	16 Sep 2020 13:30:43

US3602004

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered '1980'	System	16 Sep 2020 13:30:43

US3602004

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:08:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 17:11:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 17:11:45
Data point term sent to Coder	System	28 Sep 2020 17:10:41
User entered 'Hypercholesterolemia'	(b) (4), (b) (6)	28 Sep 2020 17:10:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	28 Sep 2020 17:09:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Sep 2020 13:31:20

US3602004

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:10:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	28 Sep 2020 17:09:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Sep 2020 13:31:20

US3602004

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:10:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	28 Sep 2020 17:09:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Sep 2020 13:31:20

US3602004

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:08:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:10:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	28 Sep 2020 17:09:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Sep 2020 13:31:20

US3602004

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:10:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	28 Sep 2020 17:09:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Sep 2020 13:31:20

US3602004

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:08:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:10:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	28 Sep 2020 17:09:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Sep 2020 13:31:20

US3602004

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered 'Jan 2010'	System	28 Sep 2020 17:10:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	28 Sep 2020 17:09:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Sep 2020 13:31:20

US3602004

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:08:05

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered '2010'	System	28 Sep 2020 17:10:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	28 Sep 2020 17:09:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Sep 2020 13:31:20

US3602004

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:08:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered empty.	System	28 Sep 2020 17:10:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	28 Sep 2020 17:09:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Sep 2020 13:31:20

US3602004

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:08:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered empty.	System	28 Sep 2020 17:10:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	28 Sep 2020 17:09:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Sep 2020 13:31:20

US3602004

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:08:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 17:12:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 17:12:46
Data point term sent to Coder	System	28 Sep 2020 17:11:43
User entered 'Myocardial Infarction'	(b) (4), (b) (6)	28 Sep 2020 17:11:13

US3602004

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:11:13

US3602004

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:11:13

US3602004

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:08:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:11:13

US3602004

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:08:05

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:11:13

US3602004

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:08:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:11:13

US3602004

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:08:05

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered 'Jan 2010'	System	28 Sep 2020 17:11:13

US3602004

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:08:05

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered '2010'	System	28 Sep 2020 17:11:13

US3602004

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:08:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered 'Jan 2010'	System	28 Sep 2020 17:11:13

US3602004

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:08:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered '2010'	System	28 Sep 2020 17:11:13

US3602004

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:08:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Presyncope, LLT: Vasovagal reaction - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 17:13:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 17:13:47
Data point term sent to Coder	System	28 Sep 2020 17:12:45
User entered 'Vasovagal Episode'	(b) (4), (b) (6)	28 Sep 2020 17:11:55

US3602004

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'UN UNK 2011'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:11:55

US3602004

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:11:55

US3602004

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:08:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:11:55

US3602004

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:08:05

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'UN UNK 2011'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:11:55

US3602004

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:08:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:11:55

US3602004

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:08:05

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered 'Jan 2011'	System	28 Sep 2020 17:11:55

US3602004

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:08:05

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered '2011'	System	28 Sep 2020 17:11:55

US3602004

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:08:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered 'Jan 2011'	System	28 Sep 2020 17:11:55

US3602004

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:08:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered '2011'	System	28 Sep 2020 17:11:55

US3602004

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:08:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Presyncope, LLT: Vasovagal reaction - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 17:13:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 17:13:48
Data point term sent to Coder	System	28 Sep 2020 17:12:46
User entered 'Vasovagal Episode'	(b) (4), (b) (6)	28 Sep 2020 17:12:23

US3602004

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'UN UNK 2012'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:12:23

US3602004

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:12:23

US3602004

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:08:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:12:23

US3602004

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:08:05

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'UN UNK 2012'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:12:23

US3602004

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:08:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:12:23

US3602004

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:08:05

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered 'Jan 2012'	System	28 Sep 2020 17:12:23

US3602004

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:08:05

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered '2012'	System	28 Sep 2020 17:12:23

US3602004

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:08:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered 'Jan 2012'	System	28 Sep 2020 17:12:23

US3602004

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:08:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered '2012'	System	28 Sep 2020 17:12:23

US3602004

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:08:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal spastic and hypermotility disorders, PT: Irritable bowel syndrome, LLT: Irritable bowel syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 17:14:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 17:14:39
Data point term sent to Coder	System	28 Sep 2020 17:13:48
User entered 'Irritable Bowel Syndrome'	(b) (4), (b) (6)	28 Sep 2020 17:12:57

US3602004

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'UN UNK 2009'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:12:57

US3602004

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:12:57

US3602004

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:08:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:12:57

US3602004

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:08:05

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:12:57

US3602004

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:08:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:12:57

US3602004

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:08:05

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered 'Jan 2009'	System	28 Sep 2020 17:12:57

US3602004

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:08:05

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered '2009'	System	28 Sep 2020 17:12:57

US3602004

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:08:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered empty.	System	28 Sep 2020 17:12:57

US3602004

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:08:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered empty.	System	28 Sep 2020 17:12:57

US3602004

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:08:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Restless legs syndrome, LLT: Restless leg syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 17:16:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 17:16:56
Data point term sent to Coder	System	28 Sep 2020 17:15:55
User entered 'Restless Leg Syndrome'	(b) (4), (b) (6)	28 Sep 2020 17:15:21

US3602004

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:15:21

US3602004

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:15:21

US3602004

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:08:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:15:21

US3602004

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:08:05

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:15:21

US3602004

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:08:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:15:21

US3602004

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:08:05

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered 'Jan 2010'	System	28 Sep 2020 17:15:21

US3602004

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:08:05

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered '2010'	System	28 Sep 2020 17:15:21

US3602004

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:08:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered empty.	System	28 Sep 2020 17:15:21

US3602004

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:08:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered empty.	System	28 Sep 2020 17:15:21

US3602004

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:08:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopausal - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 18:31:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 18:31:24
Data point term sent to Coder	System	09 Oct 2020 18:31:12
User entered 'Menopausal'	(b) (4), (b) (6)	09 Oct 2020 18:30:55

US3602004

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'UN UNK 2012'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:30:55

US3602004

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:30:55

US3602004

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:08:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:30:55

US3602004

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:08:05

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:30:55

US3602004

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:08:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:30:55

US3602004

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:08:05

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered 'Jan 2012'	System	09 Oct 2020 18:30:55

US3602004

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:08:05

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered '2012'	System	09 Oct 2020 18:30:55

US3602004

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:08:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered empty.	System	09 Oct 2020 18:30:55

US3602004

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:08:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered empty.	System	09 Oct 2020 18:30:55

US3602004

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:08:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 05:28:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 05:28:41
Data point term sent to Coder	System	13 Nov 2020 21:45:44
User entered 'Insomnia (self-diagnosed)'	(b) (4), (b) (6)	13 Nov 2020 21:44:59

US3602004

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'UN Jul 2020'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:44:59

US3602004

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:44:59

US3602004

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:08:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:44:59

US3602004

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:08:05

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:44:59

US3602004

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:08:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:44:59

US3602004

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:08:05

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered 'Jul 2020'	System	13 Nov 2020 21:44:59

US3602004

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:08:05

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered '2020'	System	13 Nov 2020 21:44:59

US3602004

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:08:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered empty.	System	13 Nov 2020 21:44:59

US3602004

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:08:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered empty.	System	13 Nov 2020 21:44:59

US3602004

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:08:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 05:47:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 05:47:45
Data point term sent to Coder	System	13 Nov 2020 21:46:44
User entered 'Gastroesophageal Reflux Disorder (GERD) (self-diagnosed)'	(b) (4), (b) (6)	13 Nov 2020 21:46:36

US3602004

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'UN UNK 2017'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:46:36

US3602004

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:46:36

US3602004

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:08:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:46:36

US3602004

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:08:05

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:46:36

US3602004

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:08:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:46:36

US3602004

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:08:05

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered 'Jan 2017'	System	13 Nov 2020 21:46:36

US3602004

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:08:05

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered '2017'	System	13 Nov 2020 21:46:36

US3602004

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:08:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered empty.	System	13 Nov 2020 21:46:36

US3602004

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:08:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered empty.	System	13 Nov 2020 21:46:36

US3602004

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:08:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 21:48:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 21:48:38
Data point term sent to Coder	System	13 Nov 2020 21:47:45
User entered 'Seasonal allergies'	(b) (4), (b) (6)	13 Nov 2020 21:47:27

US3602004

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'UN UNK 1980'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:47:27

US3602004

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:47:27

US3602004

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:08:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:47:27

US3602004

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:08:05

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:47:27

US3602004

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:08:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:47:27

US3602004

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:08:05

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered 'Jan 1980'	System	13 Nov 2020 21:47:27

US3602004

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:08:05

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered '1980'	System	13 Nov 2020 21:47:27

US3602004

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:08:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered empty.	System	13 Nov 2020 21:47:27

US3602004

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:08:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered empty.	System	13 Nov 2020 21:47:27

US3602004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:42:08

US3602004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '2 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:42:08

US3602004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '11:00'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:42:08

US3602004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered '2 Sep 2020 11:00'	System	02 Sep 2020 16:42:08

US3602004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '63' in reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 17:47:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 12:57:24
User entered '63' in	(b) (4), (b) (6)	02 Sep 2020 16:42:08
DataPoint set to visible.	System	02 Sep 2020 16:37:56

US3602004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '160' lb reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 17:47:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 12:57:24
User entered '160' lb	(b) (4), (b) (6)	02 Sep 2020 16:42:08
DataPoint set to visible.	System	02 Sep 2020 16:37:56

US3602004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered '28.40199'	System	14 Sep 2020 17:47:43
User entered empty.	System	14 Sep 2020 12:57:24
User entered '28.40199'	System	02 Sep 2020 16:42:08
DataPoint set to visible.	System	02 Sep 2020 16:37:56

US3602004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered 'kg/m2'	System	14 Sep 2020 17:47:43
User entered empty.	System	14 Sep 2020 12:57:24
User entered 'kg/m2'	System	02 Sep 2020 16:42:08
DataPoint set to visible.	System	02 Sep 2020 16:37:56

US3602004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Sep 2020 04:24:15
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' answered with 'Temperature reported as ND' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 12:56:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 12:56:10
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 22:37:29
User entered '98.9' F	(b) (4), (b) (6)	02 Sep 2020 16:42:08

US3602004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Sep 2020 12:56:10
User entered 'Oral (Oral)'	(b) (4), (b) (6)	02 Sep 2020 16:42:08

US3602004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:42:08

US3602004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 12:56:10
User entered '72'	(b) (4), (b) (6)	02 Sep 2020 16:42:08

US3602004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered 'bpm'	System	02 Sep 2020 16:42:08

US3602004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 12:56:10
User entered '18'	(b) (4), (b) (6)	02 Sep 2020 16:42:08

US3602004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered 'breaths/min'	System	02 Sep 2020 16:42:08

US3602004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered missing code ND - Not Done; reason for	(b) (4)	14 Sep 2020 12:56:10
change Data Entry Error	(b) (4), (b) (6)	
User entered '142'	(b) (4), (b) (6)	02 Sep 2020 16:42:08

US3602004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered 'mmHg'	System	02 Sep 2020 16:42:08

US3602004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Sep 2020 12:56:10
User entered '92'	(b) (4), (b) (6)	02 Sep 2020 16:42:08

US3602004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered 'mmHg'	System	02 Sep 2020 16:42:08

US3602004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35

US3602004

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35

US3602004

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:08:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:43:28

US3602004

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:08:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '2 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:43:28

US3602004

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:08:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '2 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:44:13

US3602004

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:08:05

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:44:13

US3602004

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:08:05

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 08:53:48
Query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH ecrf as appropriate. ' answered with 'will update' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 18:30:11
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 23:02:10
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	02 Sep 2020 16:44:13

US3602004

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:08:05

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:44:13

US3602004

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:08:05

If Surgically sterile, date of surgery (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:44:13

US3602004

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:08:05

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:44:13

US3602004

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:08:05

If Post-menopausal, date of last menstruation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'UN UNK 2012'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:44:13

US3602004

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:08:05

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:44:13

US3602004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:46:33

US3602004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:46:33

US3602004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:46:33

US3602004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:46:33

US3602004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:46:33

US3602004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:46:33

US3602004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:46:33

US3602004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:46:33

US3602004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:46:33

US3602004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:51:30
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 16:46:33

US3602004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:46:33

US3602004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:46:33

US3602004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:46:33

US3602004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:46:33

US3602004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:46:33

US3602004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:46:33

US3602004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:50:54
User entered '1'	(b) (4), (b) (6)	02 Sep 2020 16:46:33

US3602004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:50:54
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 16:46:33

US3602004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:46:33

US3602004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:46:33

US3602004

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:46:33

US3602004

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:46:50

US3602004

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '2 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:46:50

US3602004

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:46:50

US3602004

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'VISIT1'	System	02 Sep 2020 16:46:50

US3602004

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:08:05

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '02 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 16:09:25

US3602004

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:08:05

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '145584'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 16:09:25

US3602004

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:08:05

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 16:09:25

US3602004

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:08:05

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)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:50:28

US3602004

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:08:05

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)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:50:28

US3602004

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:08:05

[Severe obesity \(body mass index > or = 40kg/m2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:50:28

US3602004

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:08:05

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:50:28

US3602004

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:08:05

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:50:28

US3602004

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:08:05

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:24:09
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 04:54:19
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 04:54:19

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:08:05

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Sep 2020 10:30:11
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 17:47:15
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'Screening vitals reported as ND.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 12:57:46
User entered '63' in reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 12:56:51
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 22:37:07
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:08:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 17:47:15
User entered '160' lb reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 12:56:51
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:08:05

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Sep 2020 10:30:11
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 17:47:15
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'Screening vitals reported as ND.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 12:57:46
User entered '63' in reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 12:56:51
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 22:37:07
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:08:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 17:47:15
User entered '160' lb reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 12:56:51
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '2 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '11:45' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:44:13
User entered '11:00'	(b) (4), (b) (6)	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered '2 Sep 2020 11:45'	System	04 Sep 2020 13:44:13
User entered '2 Sep 2020 11:00'	System	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '98.9' F	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '72'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'bpm'	System	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '19' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:44:13
User entered '18'	(b) (4), (b) (6)	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'breaths/min'	System	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '142'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'mmHg'	System	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '92'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'mmHg'	System	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:08:05

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Sep 2020 10:30:11
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 17:47:15
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'Screening vitals reported as ND.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 12:57:46
User entered '63' in reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 12:56:51
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 22:37:07
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:08:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 17:47:15
User entered '160' lb reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 12:56:51
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Sep 2020 18:33:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 18:33:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 18:33:43
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 18:04:17
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '2 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:33:43
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '13:55' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:33:43
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered '2 Sep 2020 13:55'	System	02 Sep 2020 18:33:43
User entered empty.	System	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '98.7' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:33:43
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:33:43
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '64' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:33:43
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'bpm'	System	02 Sep 2020 18:33:43
User entered empty.	System	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '18' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:33:43
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'breaths/min'	System	02 Sep 2020 18:33:43
User entered empty.	System	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '118' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:33:43
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'mmHg'	System	02 Sep 2020 18:33:43
User entered empty.	System	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '68' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:33:43
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'mmHg'	System	02 Sep 2020 18:33:43
User entered empty.	System	02 Sep 2020 18:04:17

US3602004

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:08:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:47:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 18:05:48

US3602004

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:08:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:47:23
User entered '2 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 18:05:48

US3602004

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:22:59

US3602004

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:22:59

US3602004

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

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)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:22:59

US3602004

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 18:22:59

US3602004

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '2 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:22:59

US3602004

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '13:25' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:42:40
User entered '14:32' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 13:42:19
User entered '13:25'	(b) (4), (b) (6)	02 Sep 2020 18:22:59

US3602004

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered '2 Sep 2020 13:25'	System	04 Sep 2020 13:42:40
User entered '2 Sep 2020 14:32'	System	04 Sep 2020 13:42:19
User entered '2 Sep 2020 13:25'	System	02 Sep 2020 18:22:59

US3602004

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:22:59

US3602004

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'ONCE'	System	02 Sep 2020 18:22:59

US3602004

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 18:22:59

US3602004

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:23:37

US3602004

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '2 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:23:37

US3602004

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '12:30'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:23:37

US3602004

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered '2 Sep 2020 12:30'	System	02 Sep 2020 18:23:37

US3602004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:08:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '2 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:24:03

US3602004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:08:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	02 Sep 2020 18:24:03

US3602004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:08:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:24:03

US3602004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:08:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '12:30'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:24:03

US3602004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:08:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered '2 Sep 2020 12:30'	System	02 Sep 2020 18:24:03

US3602004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:08:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	02 Sep 2020 18:24:03

US3602004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:08:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 18:24:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 18:24:08
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 18:24:03
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 18:24:03

US3602004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:08:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:24:03

US3602004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:08:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered empty.	System	02 Sep 2020 18:24:03

US3602004

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 18:24:17

US3602004

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'I'	System	02 Sep 2020 18:24:17

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	02 Sep 2020 18:22:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-02T14:25:39', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '6d8f4dad-27a7-4a97-bd15-a96c26866469'	System	02 Sep 2020 18:26:07
User entered 'Yes (Y)'	System	02 Sep 2020 18:26:07

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-02T14:25:52', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '6d8f4dad-27a7-4a97-bd15-a96c26866469'	System	02 Sep 2020 18:26:07
User entered '98.7'	System	02 Sep 2020 18:26:07

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-02T14:25:58', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '6d8f4dad-27a7-4a97-bd15-a96c26866469'	System	02 Sep 2020 18:26:07
User entered 'No (N)'	System	02 Sep 2020 18:26:07

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-02T14:26:04', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '6d8f4dad-27a7-4a97-bd15-a96c26866469'	System	02 Sep 2020 18:26:07
User entered '02 Sep 2020 14:26'	System	02 Sep 2020 18:26:07

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '02 Sep 2020 13:45'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '02 Sep 2020 16:15'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	02 Sep 2020 18:22:59
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-02T21:02:37', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '9d2a529a-f545-429d-b379-1ebbfea80899'	System	03 Sep 2020 01:03:02
User entered 'Yes (Y)'	System	03 Sep 2020 01:03:02

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-02T21:02:46', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '9d2a529a-f545-429d-b379-1ebbfea80899'	System	03 Sep 2020 01:03:02
User entered '97.2'	System	03 Sep 2020 01:03:02

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-02T21:02:52', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '9d2a529a-f545-429d-b379-1ebbfea80899'	System	03 Sep 2020 01:03:02
User entered 'No (N)'	System	03 Sep 2020 01:03:02

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-02T21:03:01', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '9d2a529a-f545-429d-b379-1ebbfea80899'	System	03 Sep 2020 01:03:02
User entered '02 Sep 2020 21:03'	System	03 Sep 2020 01:03:02

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '02 Sep 2020 17:10'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	02 Sep 2020 18:22:59
User entered 'Day 2'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-03T14:25:33', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '418d25f9-e7a2-4b9f-bc76-72e4ff1492a5'	System	03 Sep 2020 18:26:14
User entered 'Yes (Y)'	System	03 Sep 2020 18:26:14

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-03T14:25:48', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '418d25f9-e7a2-4b9f-bc76-72e4ff1492a5'	System	03 Sep 2020 18:26:14
User entered '98.2'	System	03 Sep 2020 18:26:14

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-03T14:25:54', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '418d25f9-e7a2-4b9f-bc76-72e4ff1492a5'	System	03 Sep 2020 18:26:14
User entered 'Yes (Y)'	System	03 Sep 2020 18:26:14

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Advil was confirmed (by the provider and in EMR) and then documented as being taken in Concaomitant Medication. ' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 04:07:58
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	03 Sep 2020 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-03T14:26:05', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '418d25f9-e7a2-4b9f-bc76-72e4ff1492a5'	System	03 Sep 2020 18:26:14
User entered '1'	System	03 Sep 2020 18:26:14

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-03T14:26:05', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '418d25f9-e7a2-4b9f-bc76-72e4ff1492a5' User entered '0'	System	03 Sep 2020 18:26:14
	System	03 Sep 2020 18:26:14

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-03T14:26:11', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '418d25f9-e7a2-4b9f-bc76-72e4ff1492a5'	System	03 Sep 2020 18:26:14
User entered '03 Sep 2020 14:26'	System	03 Sep 2020 18:26:14

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	02 Sep 2020 18:22:59
User entered 'Day 3'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:08:05

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-04T13:00:35', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'e7cd2ea3-e56b-4dcf-9f8a-6f20f437466d'	System	04 Sep 2020 17:02:00
User entered 'Yes (Y)'	System	04 Sep 2020 17:02:00

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:08:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-04T13:00:42', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'e7cd2ea3-e56b-4dcf-9f8a-6f20f437466d' User entered '97.6'	System	04 Sep 2020 17:02:00
	System	04 Sep 2020 17:02:00

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:08:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-04T13:00:51', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'e7cd2ea3-e56b-4dcf-9f8a-6f20f437466d'	System	04 Sep 2020 17:02:00
User entered 'Yes (Y)'	System	04 Sep 2020 17:02:00

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:08:05

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Advil was confirmed (by the provider and in EMR) and then documented as being taken in Concaomitant Medication. ' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 05:09:23
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 12:59:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-04T13:01:02', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'e7cd2ea3-e56b-4dcf-9f8a-6f20f437466d'	System	04 Sep 2020 17:02:00
User entered '1'	System	04 Sep 2020 17:02:00

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:08:05

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-04T13:01:02', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'e7cd2ea3-e56b-4dcf-9f8a-6f20f437466d' User entered '0'	System	04 Sep 2020 17:02:00
	System	04 Sep 2020 17:02:00

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-04T13:01:07', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'e7cd2ea3-e56b-4dcf-9f8a-6f20f437466d' User entered '04 Sep 2020 13:01'	System	04 Sep 2020 17:02:00
	System	04 Sep 2020 17:02:00

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	02 Sep 2020 18:22:59
User entered 'Day 4'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:08:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-05T20:00:06', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '3a659231-bbdb-4c13-8641-df5fed814f8c'	System	06 Sep 2020 00:00:43
User entered 'Yes (Y)'	System	06 Sep 2020 00:00:43

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:08:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-05T20:00:12', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '3a659231-bbdb-4c13-8641-df5fed814f8c'	System	06 Sep 2020 00:00:43
User entered '97.5'	System	06 Sep 2020 00:00:43

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:08:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-05T20:00:34', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '3a659231-bbdb-4c13-8641-df5fed814f8c'	System	06 Sep 2020 00:00:43
User entered 'No (N)'	System	06 Sep 2020 00:00:43

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-05T20:00:39', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '3a659231-bbdb-4c13-8641-df5fed814f8c'	System	06 Sep 2020 00:00:43
User entered '05 Sep 2020 20:00'	System	06 Sep 2020 00:00:43

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	02 Sep 2020 18:22:59
User entered 'Day 5'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:08:05

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-06T21:18:53', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '38b8d368-862c-4d3a-8b98-7cd27a2c81dc'	System	07 Sep 2020 01:20:10
User entered 'Yes (Y)'	System	07 Sep 2020 01:20:10

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:08:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-06T21:19:23', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '38b8d368-862c-4d3a-8b98-7cd27a2c81dc'	System	07 Sep 2020 01:20:10
User entered '96.8'	System	07 Sep 2020 01:20:10

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:08:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-06T21:19:51', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '38b8d368-862c-4d3a-8b98-7cd27a2c81dc'	System	07 Sep 2020 01:20:10
User entered 'No (N)'	System	07 Sep 2020 01:20:10

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-06T21:19:59', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '38b8d368-862c-4d3a-8b98-7cd27a2c81dc'	System	07 Sep 2020 01:20:10
User entered '06 Sep 2020 21:19'	System	07 Sep 2020 01:20:10

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	02 Sep 2020 18:22:59
User entered 'Day 6'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:08:05

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-07T20:26:15', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '054712e1-80ac-4526-a8e8-59996e1a7435'	System	08 Sep 2020 00:26:50
User entered 'Yes (Y)'	System	08 Sep 2020 00:26:50

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:08:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-07T20:26:21', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '054712e1-80ac-4526-a8e8-59996e1a7435' User entered '97.5'	System	08 Sep 2020 00:26:50
	System	08 Sep 2020 00:26:50

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:08:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-07T20:26:31', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '054712e1-80ac-4526-a8e8-59996e1a7435'	System	08 Sep 2020 00:26:50
User entered 'Yes (Y)'	System	08 Sep 2020 00:26:50

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:08:05

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Advil was confirmed (by the provider and in EMR) and then documented as being taken in Concaomitant Medication. ' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 04:03:28
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	08 Sep 2020 00:26:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-07T20:26:38', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '054712e1-80ac-4526-a8e8-59996e1a7435'	System	08 Sep 2020 00:26:50
User entered '1'	System	08 Sep 2020 00:26:50

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:08:05

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-07T20:26:38', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '054712e1-80ac-4526-a8e8-59996e1a7435'	System	08 Sep 2020 00:26:50
User entered '0'	System	08 Sep 2020 00:26:50

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-07T20:26:45', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '054712e1-80ac-4526-a8e8-59996e1a7435'	System	08 Sep 2020 00:26:50
User entered '07 Sep 2020 20:26'	System	08 Sep 2020 00:26:50

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	02 Sep 2020 18:22:59
User entered 'Day 7'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:08:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-08T21:58:20', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '548ee63f-6957-4436-a2a9-d43e079cb021'	System	09 Sep 2020 01:58:38
User entered 'Yes (Y)'	System	09 Sep 2020 01:58:38

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:08:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-08T21:58:26', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '548ee63f-6957-4436-a2a9-d43e079cb021'	System	09 Sep 2020 01:58:38
User entered '97.6'	System	09 Sep 2020 01:58:38

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:08:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-08T21:58:30', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '548ee63f-6957-4436-a2a9-d43e079cb021'	System	09 Sep 2020 01:58:38
User entered 'No (N)'	System	09 Sep 2020 01:58:38

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-08T21:58:35', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '548ee63f-6957-4436-a2a9-d43e079cb021'	System	09 Sep 2020 01:58:38
User entered '08 Sep 2020 21:58'	System	09 Sep 2020 01:58:38

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	02 Sep 2020 18:22:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-02T14:26:14', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ec2d7fef-3c2a-4d0a-9a0b-1d0c12019083'	System	02 Sep 2020 18:27:03
User entered 'None (1)'	System	02 Sep 2020 18:27:03

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-02T14:26:37', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ec2d7fef-3c2a-4d0a-9a0b-1d0c12019083'	System	02 Sep 2020 18:27:03
User entered 'No (N)'	System	02 Sep 2020 18:27:03

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-02T14:26:42', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ec2d7fef-3c2a-4d0a-9a0b-1d0c12019083'	System	02 Sep 2020 18:27:03
User entered 'No (N)'	System	02 Sep 2020 18:27:03

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-02T14:26:56', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ec2d7fef-3c2a-4d0a-9a0b-1d0c12019083'	System	02 Sep 2020 18:27:03
User entered 'None (1)'	System	02 Sep 2020 18:27:03

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-02T14:27:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ec2d7fef-3c2a-4d0a-9a0b-1d0c12019083'	System	02 Sep 2020 18:27:03
User entered '02 Sep 2020 14:27'	System	02 Sep 2020 18:27:03

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '02 Sep 2020 13:45'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '02 Sep 2020 16:15'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	02 Sep 2020 18:22:59
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-02T21:03:25', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ddc05454-23e6-4926-ac26-9be3d8be6eb2'	System	03 Sep 2020 01:04:14
User entered 'None (1)'	System	03 Sep 2020 01:04:14

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-02T21:03:31', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ddc05454-23e6-4926-ac26-9be3d8be6eb2'	System	03 Sep 2020 01:04:14
User entered 'No (N)'	System	03 Sep 2020 01:04:14

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-02T21:03:46', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ddc05454-23e6-4926-ac26-9be3d8be6eb2'	System	03 Sep 2020 01:04:14
User entered 'No (N)'	System	03 Sep 2020 01:04:14

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-02T21:04:07', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ddc05454-23e6-4926-ac26-9be3d8be6eb2'	System	03 Sep 2020 01:04:14
User entered 'None (1)'	System	03 Sep 2020 01:04:14

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-02T21:04:12', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ddc05454-23e6-4926-ac26-9be3d8be6eb2'	System	03 Sep 2020 01:04:14
User entered '02 Sep 2020 21:04'	System	03 Sep 2020 01:04:14

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '02 Sep 2020 17:10'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	02 Sep 2020 18:22:59
User entered 'Day 2'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-03T14:26:27', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'cc4302a0-e673-4082-9cf2-3b2710158626'	System	03 Sep 2020 18:26:57
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 18:26:57

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-03T14:26:29', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'cc4302a0-e673-4082-9cf2-3b2710158626'	System	03 Sep 2020 18:26:57
User entered 'No (N)'	System	03 Sep 2020 18:26:57

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

Is there any any SWELLING/HARDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-03T14:26:32', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'cc4302a0-e673-4082-9cf2-3b2710158626'	System	03 Sep 2020 18:26:57
User entered 'No (N)'	System	03 Sep 2020 18:26:57

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-03T14:26:43', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'cc4302a0-e673-4082-9cf2-3b2710158626'	System	03 Sep 2020 18:26:57
User entered 'None (1)'	System	03 Sep 2020 18:26:57

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-03T14:26:49', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'cc4302a0-e673-4082-9cf2-3b2710158626'	System	03 Sep 2020 18:26:57
User entered '03 Sep 2020 14:26'	System	03 Sep 2020 18:26:57

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	02 Sep 2020 18:22:59
User entered 'Day 3'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-04T12:59:33', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '486eac67-eee2-4028-9bd0-b490fe93eb0f'	System	04 Sep 2020 17:00:30
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 17:00:30

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-04T12:59:37', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '486eac67-eee2-4028-9bd0-b490fe93eb0f'	System	04 Sep 2020 17:00:30
User entered 'No (N)'	System	04 Sep 2020 17:00:30

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-04T12:59:44', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '486eac67-eee2-4028-9bd0-b490fe93eb0f'	System	04 Sep 2020 17:00:30
User entered 'No (N)'	System	04 Sep 2020 17:00:30

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-04T13:00:10', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '486eac67-eee2-4028-9bd0-b490fe93eb0f'	System	04 Sep 2020 17:00:30
User entered 'None (1)'	System	04 Sep 2020 17:00:30

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-04T13:00:15', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '486eac67-eee2-4028-9bd0-b490fe93eb0f'	System	04 Sep 2020 17:00:30
User entered '04 Sep 2020 13:00'	System	04 Sep 2020 17:00:30

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	02 Sep 2020 18:22:59
User entered 'Day 4'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-05T20:00:45', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'f6ff30ca-75e3-402b-bc8e-61316e2124a4'	System	06 Sep 2020 00:01:02
User entered 'None (1)'	System	06 Sep 2020 00:01:02

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-05T20:00:48', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'f6ff30ca-75e3-402b-bc8e-61316e2124a4'	System	06 Sep 2020 00:01:02
User entered 'No (N)'	System	06 Sep 2020 00:01:02

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-05T20:00:51', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'f6ff30ca-75e3-402b-bc8e-61316e2124a4'	System	06 Sep 2020 00:01:02
User entered 'No (N)'	System	06 Sep 2020 00:01:02

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-05T20:00:57', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'f6ff30ca-75e3-402b-bc8e-61316e2124a4'	System	06 Sep 2020 00:01:02
User entered 'None (1)'	System	06 Sep 2020 00:01:02

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-05T20:01:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'f6ff30ca-75e3-402b-bc8e-61316e2124a4'	System	06 Sep 2020 00:01:02
User entered '05 Sep 2020 20:01'	System	06 Sep 2020 00:01:02

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	02 Sep 2020 18:22:59
User entered 'Day 5'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-06T21:20:15', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '7110f3ae-106b-4087-9f2d-f211bed43a72'	System	07 Sep 2020 01:21:41
User entered 'None (1)'	System	07 Sep 2020 01:21:41

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-06T21:20:19', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '7110f3ae-106b-4087-9f2d-f211bed43a72'	System	07 Sep 2020 01:21:41
User entered 'No (N)'	System	07 Sep 2020 01:21:41

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-06T21:20:24', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '7110f3ae-106b-4087-9f2d-f211bed43a72'	System	07 Sep 2020 01:21:41
User entered 'No (N)'	System	07 Sep 2020 01:21:41

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-06T21:21:14', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '7110f3ae-106b-4087-9f2d-f211bed43a72'	System	07 Sep 2020 01:21:41
User entered 'None (1)'	System	07 Sep 2020 01:21:41

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-06T21:21:38', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '7110f3ae-106b-4087-9f2d-f211bed43a72'	System	07 Sep 2020 01:21:41
User entered '06 Sep 2020 21:21'	System	07 Sep 2020 01:21:41

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	02 Sep 2020 18:22:59
User entered 'Day 6'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-07T20:26:52', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '2089ec89-ae03-453e-9e78-03d67421e19e'	System	08 Sep 2020 00:27:38
User entered 'None (1)'	System	08 Sep 2020 00:27:38

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-07T20:26:56', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '2089ec89-ae03-453e-9e78-03d67421e19e'	System	08 Sep 2020 00:27:38
User entered 'No (N)'	System	08 Sep 2020 00:27:38

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-07T20:27:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '2089ec89-ae03-453e-9e78-03d67421e19e'	System	08 Sep 2020 00:27:38
User entered 'No (N)'	System	08 Sep 2020 00:27:38

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-07T20:27:27', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '2089ec89-ae03-453e-9e78-03d67421e19e'	System	08 Sep 2020 00:27:38
User entered 'None (1)'	System	08 Sep 2020 00:27:38

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-07T20:27:34', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '2089ec89-ae03-453e-9e78-03d67421e19e'	System	08 Sep 2020 00:27:38
User entered '07 Sep 2020 20:27'	System	08 Sep 2020 00:27:38

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	02 Sep 2020 18:22:59
User entered 'Day 7'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-08T21:58:41', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '8bae2afc-528e-4f62-bb5e-7e69bafcb5bf'	System	09 Sep 2020 01:59:00
User entered 'None (1)'	System	09 Sep 2020 01:59:00

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-08T21:58:44', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '8bae2afc-528e-4f62-bb5e-7e69bafcb5bf'	System	09 Sep 2020 01:59:00
User entered 'No (N)'	System	09 Sep 2020 01:59:00

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-08T21:58:46', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '8bae2afc-528e-4f62-bb5e-7e69bafcb5bf'	System	09 Sep 2020 01:59:00
User entered 'No (N)'	System	09 Sep 2020 01:59:00

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-08T21:58:50', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '8bae2afc-528e-4f62-bb5e-7e69bafcb5bf'	System	09 Sep 2020 01:59:00
User entered 'None (1)'	System	09 Sep 2020 01:59:00

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-08T21:58:57', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '8bae2afc-528e-4f62-bb5e-7e69bafcb5bf'	System	09 Sep 2020 01:59:00
User entered '08 Sep 2020 21:58'	System	09 Sep 2020 01:59:00

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	02 Sep 2020 18:22:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-02T14:27:14', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '5b92abe1-daf6-4a41-be5b-12def9eee139'	System	02 Sep 2020 18:27:53
User entered 'None (0)'	System	02 Sep 2020 18:27:53

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-02T14:27:18', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '5b92abe1-daf6-4a41-be5b-12def9eee139'	System	02 Sep 2020 18:27:53
User entered 'None (0)'	System	02 Sep 2020 18:27:53

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-02T14:27:22', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '5b92abe1-daf6-4a41-be5b-12def9eee139'	System	02 Sep 2020 18:27:53
User entered 'None (0)'	System	02 Sep 2020 18:27:53

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-02T14:27:26', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '5b92abe1-daf6-4a41-be5b-12def9eee139'	System	02 Sep 2020 18:27:53
User entered 'None (0)'	System	02 Sep 2020 18:27:53

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-02T14:27:30', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '5b92abe1-daf6-4a41-be5b-12def9eee139'	System	02 Sep 2020 18:27:53
User entered 'None (0)'	System	02 Sep 2020 18:27:53

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-02T14:27:34', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '5b92abe1-daf6-4a41-be5b-12def9eee139'	System	02 Sep 2020 18:27:53
User entered 'None (0)'	System	02 Sep 2020 18:27:53

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-02T14:27:48', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '5b92abe1-daf6-4a41-be5b-12def9eee139'	System	02 Sep 2020 18:27:53
User entered 'No (N)'	System	02 Sep 2020 18:27:53

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-02T14:27:52', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '5b92abe1-daf6-4a41-be5b-12def9eee139'	System	02 Sep 2020 18:27:53
User entered '02 Sep 2020 14:27'	System	02 Sep 2020 18:27:53

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '02 Sep 2020 13:45'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '02 Sep 2020 16:15'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	02 Sep 2020 18:22:59
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-02T21:04:20', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '96d70541-cc3a-46e3-8668-705cc6858a88'	System	03 Sep 2020 01:05:11
User entered 'None (0)'	System	03 Sep 2020 01:05:11

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-02T21:04:25', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '96d70541-cc3a-46e3-8668-705cc6858a88'	System	03 Sep 2020 01:05:11
User entered 'None (0)'	System	03 Sep 2020 01:05:11

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-02T21:04:36', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '96d70541-cc3a-46e3-8668-705cc6858a88'	System	03 Sep 2020 01:05:11
User entered 'None (0)'	System	03 Sep 2020 01:05:11

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-02T21:04:45', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '96d70541-cc3a-46e3-8668-705cc6858a88'	System	03 Sep 2020 01:05:11
User entered 'None (0)'	System	03 Sep 2020 01:05:11

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-02T21:04:49', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '96d70541-cc3a-46e3-8668-705cc6858a88'	System	03 Sep 2020 01:05:11
User entered 'None (0)'	System	03 Sep 2020 01:05:11

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-02T21:04:54', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '96d70541-cc3a-46e3-8668-705cc6858a88'	System	03 Sep 2020 01:05:11
User entered 'None (0)'	System	03 Sep 2020 01:05:11

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-02T21:05:01', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '96d70541-cc3a-46e3-8668-705cc6858a88'	System	03 Sep 2020 01:05:11
User entered 'No (N)'	System	03 Sep 2020 01:05:11

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-02T21:05:10', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '96d70541-cc3a-46e3-8668-705cc6858a88'	System	03 Sep 2020 01:05:11
User entered '02 Sep 2020 21:05'	System	03 Sep 2020 01:05:11

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '02 Sep 2020 17:10'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	02 Sep 2020 18:22:59
User entered 'Day 2'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-03T14:26:55', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '43d00f6f-ab82-4839-8ba2-729dd466f438'	System	03 Sep 2020 18:27:37
User entered 'None (0)'	System	03 Sep 2020 18:27:37

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-03T14:27:01', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '43d00f6f-ab82-4839-8ba2-729dd466f438'	System	03 Sep 2020 18:27:37
User entered 'None (0)'	System	03 Sep 2020 18:27:37

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-03T14:27:09', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '43d00f6f-ab82-4839-8ba2-729dd466f438'	System	03 Sep 2020 18:27:37
User entered 'None (0)'	System	03 Sep 2020 18:27:37

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-03T14:27:17', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '43d00f6f-ab82-4839-8ba2-729dd466f438'	System	03 Sep 2020 18:27:37
User entered 'None (0)'	System	03 Sep 2020 18:27:37

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-03T14:27:19', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '43d00f6f-ab82-4839-8ba2-729dd466f438'	System	03 Sep 2020 18:27:37
User entered 'None (0)'	System	03 Sep 2020 18:27:37

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-03T14:27:22', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '43d00f6f-ab82-4839-8ba2-729dd466f438'	System	03 Sep 2020 18:27:37
User entered 'None (0)'	System	03 Sep 2020 18:27:37

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-03T14:27:28', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '43d00f6f-ab82-4839-8ba2-729dd466f438'	System	03 Sep 2020 18:27:37
User entered 'No (N)'	System	03 Sep 2020 18:27:37

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-03T14:27:31', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '43d00f6f-ab82-4839-8ba2-729dd466f438'	System	03 Sep 2020 18:27:37
User entered '03 Sep 2020 14:27'	System	03 Sep 2020 18:27:37

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	02 Sep 2020 18:22:59
User entered 'Day 3'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-04T13:01:24', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'b82907fb-dd05-42ea-a922-bc71a0da6153'	System	04 Sep 2020 17:03:17
User entered 'None (0)'	System	04 Sep 2020 17:03:17

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-04T13:01:33', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'b82907fb-dd05-42ea-a922-bc71a0da6153'	System	04 Sep 2020 17:03:17
User entered 'No interference with activity (1)'	System	04 Sep 2020 17:03:17

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-04T13:01:38', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'b82907fb-dd05-42ea-a922-bc71a0da6153'	System	04 Sep 2020 17:03:17
User entered 'None (0)'	System	04 Sep 2020 17:03:17

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-04T13:01:52', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'b82907fb-dd05-42ea-a922-bc71a0da6153'	System	04 Sep 2020 17:03:17
User entered 'None (0)'	System	04 Sep 2020 17:03:17

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-04T13:01:57', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'b82907fb-dd05-42ea-a922-bc71a0da6153'	System	04 Sep 2020 17:03:17
User entered 'None (0)'	System	04 Sep 2020 17:03:17

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-04T13:02:03', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'b82907fb-dd05-42ea-a922-bc71a0da6153'	System	04 Sep 2020 17:03:17
User entered 'None (0)'	System	04 Sep 2020 17:03:17

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-04T13:02:08', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'b82907fb-dd05-42ea-a922-bc71a0da6153'	System	04 Sep 2020 17:03:17
User entered 'No (N)'	System	04 Sep 2020 17:03:17

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-04T13:02:12', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'b82907fb-dd05-42ea-a922-bc71a0da6153'	System	04 Sep 2020 17:03:17
User entered '04 Sep 2020 13:02'	System	04 Sep 2020 17:03:17

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	02 Sep 2020 18:22:59
User entered 'Day 4'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-05T20:01:06', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'fd56ba1d-e879-42f8-9f95-c5a5e7e7a9ec'	System	06 Sep 2020 00:01:56
User entered 'None (0)'	System	06 Sep 2020 00:01:56

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-05T20:01:14', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'fd56ba1d-e879-42f8-9f95-c5a5e7e7a9ec'	System	06 Sep 2020 00:01:56
User entered 'No interference with activity (1)'	System	06 Sep 2020 00:01:56

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-05T20:01:20', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'fd56ba1d-e879-42f8-9f95-c5a5e7e7a9ec'	System	06 Sep 2020 00:01:56
User entered 'None (0)'	System	06 Sep 2020 00:01:56

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-05T20:01:30', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'fd56ba1d-e879-42f8-9f95-c5a5e7e7a9ec'	System	06 Sep 2020 00:01:56
User entered 'None (0)'	System	06 Sep 2020 00:01:56

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-05T20:01:34', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'fd56ba1d-e879-42f8-9f95-c5a5e7e7a9ec'	System	06 Sep 2020 00:01:56
User entered 'None (0)'	System	06 Sep 2020 00:01:56

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-05T20:01:36', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'fd56ba1d-e879-42f8-9f95-c5a5e7e7a9ec'	System	06 Sep 2020 00:01:56
User entered 'None (0)'	System	06 Sep 2020 00:01:56

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-05T20:01:40', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'fd56ba1d-e879-42f8-9f95-c5a5e7e7a9ec'	System	06 Sep 2020 00:01:56
User entered 'No (N)'	System	06 Sep 2020 00:01:56

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-05T20:01:53', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'fd56ba1d-e879-42f8-9f95-c5a5e7e7a9ec'	System	06 Sep 2020 00:01:56
User entered '05 Sep 2020 20:01'	System	06 Sep 2020 00:01:56

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	02 Sep 2020 18:22:59
User entered 'Day 5'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-06T21:22:11', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '1e132650-1295-4c73-ac30-60e4599c9e3a' User entered 'None (0)'	System	07 Sep 2020 01:25:33
	System	07 Sep 2020 01:25:33

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-06T21:22:25', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '1e132650-1295-4c73-ac30-60e4599c9e3a'	System	07 Sep 2020 01:25:33
User entered 'None (0)'	System	07 Sep 2020 01:25:33

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-06T21:23:45', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '1e132650-1295-4c73-ac30-60e4599c9e3a' User entered 'None (0)'	System	07 Sep 2020 01:25:33
	System	07 Sep 2020 01:25:33

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-06T21:24:47', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '1e132650-1295-4c73-ac30-60e4599c9e3a' User entered 'None (0)'	System	07 Sep 2020 01:25:33
	System	07 Sep 2020 01:25:33

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-06T21:24:55', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '1e132650-1295-4c73-ac30-60e4599c9e3a' User entered 'None (0)'	System	07 Sep 2020 01:25:33
	System	07 Sep 2020 01:25:33

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-06T21:25:03', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '1e132650-1295-4c73-ac30-60e4599c9e3a' User entered 'None (0)'	System	07 Sep 2020 01:25:33
	System	07 Sep 2020 01:25:33

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-06T21:25:15', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '1e132650-1295-4c73-ac30-60e4599c9e3a'	System	07 Sep 2020 01:25:33
User entered 'No (N)'	System	07 Sep 2020 01:25:33

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-06T21:25:29', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '1e132650-1295-4c73-ac30-60e4599c9e3a'	System	07 Sep 2020 01:25:33
User entered '06 Sep 2020 21:25'	System	07 Sep 2020 01:25:33

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	02 Sep 2020 18:22:59
User entered 'Day 6'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-07T20:27:40', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '5fb2fc11-44f7-4e9c-af23-db96f43e9d4a'	System	08 Sep 2020 00:28:23
User entered 'None (0)'	System	08 Sep 2020 00:28:23

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-07T20:27:48', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '5fb2fc11-44f7-4e9c-af23-db96f43e9d4a'	System	08 Sep 2020 00:28:23
User entered 'No interference with activity (1)'	System	08 Sep 2020 00:28:23

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-07T20:27:53', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '5fb2fc11-44f7-4e9c-af23-db96f43e9d4a'	System	08 Sep 2020 00:28:23
User entered 'None (0)'	System	08 Sep 2020 00:28:23

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-07T20:28:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '5fb2fc11-44f7-4e9c-af23-db96f43e9d4a'	System	08 Sep 2020 00:28:23
User entered 'No interference with activity (1)'	System	08 Sep 2020 00:28:23

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-07T20:28:03', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '5fb2fc11-44f7-4e9c-af23-db96f43e9d4a'	System	08 Sep 2020 00:28:23
User entered 'None (0)'	System	08 Sep 2020 00:28:23

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-07T20:28:05', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '5fb2fc11-44f7-4e9c-af23-db96f43e9d4a'	System	08 Sep 2020 00:28:23
User entered 'None (0)'	System	08 Sep 2020 00:28:23

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-07T20:28:09', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '5fb2fc11-44f7-4e9c-af23-db96f43e9d4a'	System	08 Sep 2020 00:28:23
User entered 'No (N)'	System	08 Sep 2020 00:28:23

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-07T20:28:18', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '5fb2fc11-44f7-4e9c-af23-db96f43e9d4a'	System	08 Sep 2020 00:28:23
User entered '07 Sep 2020 20:28'	System	08 Sep 2020 00:28:23

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	02 Sep 2020 18:22:59
User entered 'Day 7'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-08T21:59:02', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '49bed6c1-6f39-4cf1-aa66-fb40d5b602ea'	System	09 Sep 2020 01:59:36
User entered 'None (0)'	System	09 Sep 2020 01:59:36

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-08T21:59:05', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '49bed6c1-6f39-4cf1-aa66-fb40d5b602ea'	System	09 Sep 2020 01:59:36
User entered 'None (0)'	System	09 Sep 2020 01:59:36

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-08T21:59:09', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '49bed6c1-6f39-4cf1-aa66-fb40d5b602ea'	System	09 Sep 2020 01:59:36
User entered 'None (0)'	System	09 Sep 2020 01:59:36

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-08T21:59:13', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '49bed6c1-6f39-4cf1-aa66-fb40d5b602ea'	System	09 Sep 2020 01:59:36
User entered 'None (0)'	System	09 Sep 2020 01:59:36

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-08T21:59:16', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '49bed6c1-6f39-4cf1-aa66-fb40d5b602ea'	System	09 Sep 2020 01:59:36
User entered 'None (0)'	System	09 Sep 2020 01:59:36

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-08T21:59:20', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '49bed6c1-6f39-4cf1-aa66-fb40d5b602ea'	System	09 Sep 2020 01:59:36
User entered 'None (0)'	System	09 Sep 2020 01:59:36

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-08T21:59:24', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '49bed6c1-6f39-4cf1-aa66-fb40d5b602ea'	System	09 Sep 2020 01:59:36
User entered 'No (N)'	System	09 Sep 2020 01:59:36

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-08T21:59:34', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '49bed6c1-6f39-4cf1-aa66-fb40d5b602ea'	System	09 Sep 2020 01:59:36
User entered '08 Sep 2020 21:59'	System	09 Sep 2020 01:59:36

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 18:22:59

US3602004

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 18:22:59

US3602004

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Sep 2020 16:54:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Sep 2020 16:54:12
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 16:54:12
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 13:52:56
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 13:52:56
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 13:52:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 13:28:00

US3602004

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '9 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:54:12
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	09 Sep 2020 13:52:23
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).		09 Sep 2020 13:52:23
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 13:52:23
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	09 Sep 2020 13:28:00
User entered '7 Sep 2020'	(b) (4), (b) (6)	09 Sep 2020 13:28:00

US3602004

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	10 Sep 2020 16:54:12
reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 16:54:12
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 13:52:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Sep 2020 13:28:00

US3602004

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:28:00

US3602004

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Sep 2020 16:54:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Sep 2020 16:54:35
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 16:54:35
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 13:52:47
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 13:52:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 13:28:20

US3602004

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered '1'	System	10 Sep 2020 16:54:35
User entered empty.	System	09 Sep 2020 13:52:47
User entered '1'	System	09 Sep 2020 13:28:20

US3602004

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 12:46:07

US3602004

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	27 Mar 2021 20:18:50
Signature has been broken.	(b) (4), (b) (6)	26 Mar 2021 16:42:43
User entered '16 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 16:42:43
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '17 Sep 2020'	(b) (4)	
	(b) (4), (b) (6)	17 Sep 2020 12:46:07

US3602004

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 12:46:07

US3602004

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 12:46:07

US3602004

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 12:45:44

US3602004

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'I'	System	17 Sep 2020 12:45:44

US3602004

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:16:24

US3602004

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:16:24

US3602004

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:16:24

US3602004

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:16:24

US3602004

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:16:31

US3602004

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'I'	System	24 Sep 2020 14:16:31

US3602004

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:14:58

US3602004

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:14:58

US3602004

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:14:58

US3602004

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'VISIT2'	System	28 Sep 2020 16:14:58

US3602004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	28 Sep 2020 16:58:03

US3602004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:58:03

US3602004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:58:03

US3602004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '11:13'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:58:03

US3602004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered '28 Sep 2020 11:13'	System	28 Sep 2020 16:58:03

US3602004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 04:01:26
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per provider' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 16:58:13
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	28 Sep 2020 16:58:03
User entered '96.4' F	(b) (4), (b) (6)	28 Sep 2020 16:58:03

US3602004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:58:03

US3602004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'Temporal'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:58:03

US3602004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '61'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:58:03

US3602004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'bpm'	System	28 Sep 2020 16:58:03

US3602004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '14'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:58:03

US3602004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'breaths/min'	System	28 Sep 2020 16:58:03

US3602004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '127'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:58:03

US3602004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'mmHg'	System	28 Sep 2020 16:58:03

US3602004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '76'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:58:03

US3602004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'mmHg'	System	28 Sep 2020 16:58:03

US3602004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	28 Sep 2020 17:43:23

US3602004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:43:23

US3602004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:43:23

US3602004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '13:13'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:43:23

US3602004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered '28 Sep 2020 13:13'	System	28 Sep 2020 17:43:23

US3602004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 04:01:37
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per provider' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 17:43:34
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	28 Sep 2020 17:43:23
User entered '96.7' F	(b) (4), (b) (6)	28 Sep 2020 17:43:23

US3602004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:43:23

US3602004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'Temporal'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:43:23

US3602004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '64'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:43:23

US3602004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'bpm'	System	28 Sep 2020 17:43:23

US3602004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '16'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:43:23

US3602004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'breaths/min'	System	28 Sep 2020 17:43:23

US3602004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '140'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:43:23

US3602004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'mmHg'	System	28 Sep 2020 17:43:23

US3602004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '80'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 17:43:23

US3602004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'mmHg'	System	28 Sep 2020 17:43:23

US3602004

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:08:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:16:04

US3602004

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:08:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:16:04

US3602004

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Sep 2020 16:54:55
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 16:54:55
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 16:19:35
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:19:35

US3602004

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:19:35

US3602004

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

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)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:19:35

US3602004

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'MRNA-1273 OR PLACEBO'	System	28 Sep 2020 16:54:55
User entered empty.	System	28 Sep 2020 16:19:35

US3602004

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '28 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	28 Sep 2020 16:54:55
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:19:35

US3602004

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '12:41' reason for change: Data Entry Error	(b) (4)	28 Sep 2020 16:54:55
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:19:35

US3602004

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered '28 Sep 2020 12:41'	System	28 Sep 2020 16:54:55
User entered empty.	System	28 Sep 2020 16:19:35

US3602004

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	(b) (4)	28 Sep 2020 16:54:55
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:19:35

US3602004

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'ONCE'	System	28 Sep 2020 16:54:55
User entered empty.	System	28 Sep 2020 16:19:35

US3602004

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'INTRAMUSCULAR'	System	28 Sep 2020 16:54:55
User entered empty.	System	28 Sep 2020 16:19:35

US3602004

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:58:38

US3602004

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:58:38

US3602004

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '11:34'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:58:38

US3602004

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered '28 Sep 2020 11:34'	System	28 Sep 2020 16:58:38

US3602004

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:08:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:58:54

US3602004

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:08:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	28 Sep 2020 16:58:54

US3602004

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:08:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:58:54

US3602004

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:08:05

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '11:34'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:58:54

US3602004

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:08:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered '28 Sep 2020 11:34'	System	28 Sep 2020 16:58:54

US3602004

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:08:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	28 Sep 2020 16:58:54

US3602004

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:08:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:58:54

US3602004

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:08:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:58:54

US3602004

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:08:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered empty.	System	28 Sep 2020 16:58:54

US3602004

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:58:58

US3602004

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'I'	System	28 Sep 2020 16:58:58

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	28 Sep 2020 16:54:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-28T13:13:51', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '5d373fb2-bab7-463f-bff5-b16406ebf993'	System	28 Sep 2020 17:14:09
User entered 'Yes (Y)'	System	28 Sep 2020 17:14:09

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-28T13:13:58', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '5d373fb2-bab7-463f-bff5-b16406ebf993'	System	28 Sep 2020 17:14:09
User entered '96.7'	System	28 Sep 2020 17:14:09

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-28T13:14:02', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '5d373fb2-bab7-463f-bff5-b16406ebf993'	System	28 Sep 2020 17:14:09
User entered 'No (N)'	System	28 Sep 2020 17:14:09

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-28T13:14:07', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '5d373fb2-bab7-463f-bff5-b16406ebf993'	System	28 Sep 2020 17:14:09
User entered '28 Sep 2020 13:14'	System	28 Sep 2020 17:14:09

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '28 Sep 2020 13:01'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '28 Sep 2020 15:31'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	28 Sep 2020 16:54:55
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-28T20:16:35', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '6ad7cfec-392f-4b7b-a627-ebf3d6fcef7f'	System	29 Sep 2020 00:16:55
User entered 'Yes (Y)'	System	29 Sep 2020 00:16:55

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-28T20:16:41', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '6ad7cfec-392f-4b7b-a627-ebf3d6fcef7f'	System	29 Sep 2020 00:16:55
User entered '98.4'	System	29 Sep 2020 00:16:55

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-28T20:16:45', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '6ad7cfec-392f-4b7b-a627-ebf3d6fcef7f'	System	29 Sep 2020 00:16:55
User entered 'No (N)'	System	29 Sep 2020 00:16:55

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-28T20:16:51', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '6ad7cfec-392f-4b7b-a627-ebf3d6fcef7f' User entered '28 Sep 2020 20:16'	System	29 Sep 2020 00:16:55
	System	29 Sep 2020 00:16:55

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '28 Sep 2020 16:26'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	28 Sep 2020 16:54:55
User entered 'Day 2'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-29T18:54:11', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '908a9fc3-a45a-46f2-9196-47e5e70b48b5'	System	29 Sep 2020 22:54:53
User entered 'Yes (Y)'	System	29 Sep 2020 22:54:53

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-29T18:54:22', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '908a9fc3-a45a-46f2-9196-47e5e70b48b5'	System	29 Sep 2020 22:54:53
User entered '98.3'	System	29 Sep 2020 22:54:53

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-29T18:54:29', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '908a9fc3-a45a-46f2-9196-47e5e70b48b5'	System	29 Sep 2020 22:54:53
User entered 'Yes (Y)'	System	29 Sep 2020 22:54:53

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Per provider, on day 8 safety call subject says the soreness was resolved without medication.' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 04:30:34
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	29 Sep 2020 22:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-29T18:54:39', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '908a9fc3-a45a-46f2-9196-47e5e70b48b5'	System	29 Sep 2020 22:54:53
User entered '1'	System	29 Sep 2020 22:54:53

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-29T18:54:39', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '908a9fc3-a45a-46f2-9196-47e5e70b48b5'	System	29 Sep 2020 22:54:53
User entered '0'	System	29 Sep 2020 22:54:53

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-29T18:54:49', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '908a9fc3-a45a-46f2-9196-47e5e70b48b5'	System	29 Sep 2020 22:54:53
User entered '29 Sep 2020 18:54'	System	29 Sep 2020 22:54:53

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	28 Sep 2020 16:54:55
User entered 'Day 3'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:08:05

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-30T21:16:15', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '0c468def-32d0-4698-9c01-54876df8dba8'	System	01 Oct 2020 01:16:37
User entered 'Yes (Y)'	System	01 Oct 2020 01:16:37

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:08:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-30T21:16:23', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '0c468def-32d0-4698-9c01-54876df8dba8'	System	01 Oct 2020 01:16:37
User entered '97.2'	System	01 Oct 2020 01:16:37

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:08:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-30T21:16:29', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '0c468def-32d0-4698-9c01-54876df8dba8'	System	01 Oct 2020 01:16:37
User entered 'No (N)'	System	01 Oct 2020 01:16:37

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-30T21:16:34', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '0c468def-32d0-4698-9c01-54876df8dba8'	System	01 Oct 2020 01:16:37
User entered '30 Sep 2020 21:16'	System	01 Oct 2020 01:16:37

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	28 Sep 2020 16:54:55
User entered 'Day 4'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:08:05

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-01T20:07:22', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '4470b107-dad8-49e8-8196-647252f15620'	System	02 Oct 2020 00:07:41
User entered 'Yes (Y)'	System	02 Oct 2020 00:07:41

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:08:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-01T20:07:29', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '4470b107-dad8-49e8-8196-647252f15620'	System	02 Oct 2020 00:07:41
User entered '97.6'	System	02 Oct 2020 00:07:41

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:08:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-01T20:07:34', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '4470b107-dad8-49e8-8196-647252f15620'	System	02 Oct 2020 00:07:41
User entered 'No (N)'	System	02 Oct 2020 00:07:41

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-01T20:07:37', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '4470b107-dad8-49e8-8196-647252f15620'	System	02 Oct 2020 00:07:41
User entered '01 Oct 2020 20:07'	System	02 Oct 2020 00:07:41

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	28 Sep 2020 16:54:55
User entered 'Day 5'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:08:05

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-02T22:50:10', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '7a82dc95-5a05-48ce-9c9b-0f9161213c11'	System	03 Oct 2020 02:51:06
User entered 'Yes (Y)'	System	03 Oct 2020 02:51:06

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:08:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-02T22:50:30', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '7a82dc95-5a05-48ce-9c9b-0f9161213c11'	System	03 Oct 2020 02:51:06
User entered '97.8'	System	03 Oct 2020 02:51:06

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:08:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-02T22:50:35', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '7a82dc95-5a05-48ce-9c9b-0f9161213c11'	System	03 Oct 2020 02:51:06
User entered 'No (N)'	System	03 Oct 2020 02:51:06

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-02T22:50:38', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '7a82dc95-5a05-48ce-9c9b-0f9161213c11'	System	03 Oct 2020 02:51:06
User entered '02 Oct 2020 22:50'	System	03 Oct 2020 02:51:06

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	28 Sep 2020 16:54:55
User entered 'Day 6'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:08:05

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-03T20:09:28', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '8f82f921-8b10-4530-b0e0-f6b9447f2d29'	System	04 Oct 2020 00:09:46
User entered 'Yes (Y)'	System	04 Oct 2020 00:09:46

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:08:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-03T20:09:34', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '8f82f921-8b10-4530-b0e0-f6b9447f2d29'	System	04 Oct 2020 00:09:46
User entered '97.2'	System	04 Oct 2020 00:09:46

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:08:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-03T20:09:38', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '8f82f921-8b10-4530-b0e0-f6b9447f2d29'	System	04 Oct 2020 00:09:46
User entered 'No (N)'	System	04 Oct 2020 00:09:46

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-03T20:09:43', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '8f82f921-8b10-4530-b0e0-f6b9447f2d29'	System	04 Oct 2020 00:09:46
User entered '03 Oct 2020 20:09'	System	04 Oct 2020 00:09:46

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	28 Sep 2020 16:54:55
User entered 'Day 7'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:08:05

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-04T18:51:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '05c99d31-708c-4807-866d-5513c17aa84a'	System	04 Oct 2020 22:51:56
User entered 'Yes (Y)'	System	04 Oct 2020 22:51:56

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:08:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-04T18:51:08', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '05c99d31-708c-4807-866d-5513c17aa84a'	System	04 Oct 2020 22:51:56
User entered '97.8'	System	04 Oct 2020 22:51:56

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:08:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-04T18:51:17', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '05c99d31-708c-4807-866d-5513c17aa84a'	System	04 Oct 2020 22:51:56
User entered 'Yes (Y)'	System	04 Oct 2020 22:51:56

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:08:05

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Per provider, on day 8 safety call subject says the soreness was resolved without medication.' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 04:30:42
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	04 Oct 2020 22:51:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-04T18:51:50', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '05c99d31-708c-4807-866d-5513c17aa84a'	System	04 Oct 2020 22:51:56
User entered '1'	System	04 Oct 2020 22:51:56

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:08:05

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-04T18:51:50', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '05c99d31-708c-4807-866d-5513c17aa84a'	System	04 Oct 2020 22:51:56
User entered '0'	System	04 Oct 2020 22:51:56

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-04T18:51:55', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '05c99d31-708c-4807-866d-5513c17aa84a'	System	04 Oct 2020 22:51:56
User entered '04 Oct 2020 18:51'	System	04 Oct 2020 22:51:56

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	04 Oct 2020 22:51:56
User entered 'Day 8'	System	04 Oct 2020 22:51:56

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:08:05

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-05T21:27:44', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '38dbb8b0-f52e-44b8-8cab-66e381a23b0b'	System	06 Oct 2020 01:28:03
User entered 'Yes (Y)'	System	06 Oct 2020 01:28:03

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:08:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-05T21:27:52', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '38dbb8b0-f52e-44b8-8cab-66e381a23b0b'	System	06 Oct 2020 01:28:03
User entered '97.6'	System	06 Oct 2020 01:28:03

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:08:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-05T21:27:56', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '38dbb8b0-f52e-44b8-8cab-66e381a23b0b'	System	06 Oct 2020 01:28:03
User entered 'No (N)'	System	06 Oct 2020 01:28:03

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-05T21:28:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '38dbb8b0-f52e-44b8-8cab-66e381a23b0b' User entered '05 Oct 2020 21:28'	System	06 Oct 2020 01:28:03
	System	06 Oct 2020 01:28:03

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 22:51:56

US3602004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 22:51:56

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	28 Sep 2020 16:54:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-28T13:14:13', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '432cd807-ced5-4289-969e-ba3b20445c93'	System	28 Sep 2020 17:14:33
User entered 'None (1)'	System	28 Sep 2020 17:14:33

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-28T13:14:16', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '432cd807-ced5-4289-969e-ba3b20445c93'	System	28 Sep 2020 17:14:33
User entered 'No (N)'	System	28 Sep 2020 17:14:33

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-28T13:14:19', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '432cd807-ced5-4289-969e-ba3b20445c93'	System	28 Sep 2020 17:14:33
User entered 'No (N)'	System	28 Sep 2020 17:14:33

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-28T13:14:24', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '432cd807-ced5-4289-969e-ba3b20445c93'	System	28 Sep 2020 17:14:33
User entered 'None (1)'	System	28 Sep 2020 17:14:33

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-28T13:14:30', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '432cd807-ced5-4289-969e-ba3b20445c93'	System	28 Sep 2020 17:14:33
User entered '28 Sep 2020 13:14'	System	28 Sep 2020 17:14:33

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '28 Sep 2020 13:01'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '28 Sep 2020 15:31'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	28 Sep 2020 16:54:55
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-28T20:17:07', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'e27d736e-aef1-4743-9493-ecdb6dcc4a2c'	System	29 Sep 2020 00:17:41
User entered 'Does not interfere with activity (2)'	System	29 Sep 2020 00:17:41

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-28T20:17:21', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'e27d736e-aef1-4743-9493-ecdb6dcc4a2c'	System	29 Sep 2020 00:17:41
User entered 'No (N)'	System	29 Sep 2020 00:17:41

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

Is there any SWELLING/HARDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-28T20:17:25', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'e27d736e-aef1-4743-9493-ecdb6dcc4a2c'	System	29 Sep 2020 00:17:41
User entered 'No (N)'	System	29 Sep 2020 00:17:41

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-28T20:17:32', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'e27d736e-aef1-4743-9493-ecdb6dcc4a2c'	System	29 Sep 2020 00:17:41
User entered 'None (1)'	System	29 Sep 2020 00:17:41

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-28T20:17:39', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'e27d736e-aef1-4743-9493-ecdb6dcc4a2c'	System	29 Sep 2020 00:17:41
User entered '28 Sep 2020 20:17'	System	29 Sep 2020 00:17:41

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '28 Sep 2020 16:26'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	28 Sep 2020 16:54:55
User entered 'Day 2'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-29T18:55:21', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '3426e09c-35b4-486d-bfd7-8857cb8fdcf2'	System	29 Sep 2020 23:00:20
User entered 'Does not interfere with activity (2)'	System	29 Sep 2020 23:00:20

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-29T18:55:27', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '3426e09c-35b4-486d-bfd7-8857cb8fd2'	System	29 Sep 2020 23:00:20
User entered 'Yes (Y)'	System	29 Sep 2020 23:00:20

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-29T18:58:32', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '3426e09c-35b4-486d-bfd7-8857cb8fdcf2'	System	29 Sep 2020 23:00:20
User entered '3'	System	29 Sep 2020 23:00:20

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

Is there any any SWELLING/HARDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-29T18:58:46', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '3426e09c-35b4-486d-bfd7-8857cb8fd2'	System	29 Sep 2020 23:00:20
User entered 'Yes (Y)'	System	29 Sep 2020 23:00:20

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-29T18:59:33', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '3426e09c-35b4-486d-bfd7-8857cb8fdcf2'	System	29 Sep 2020 23:00:20
User entered '4'	System	29 Sep 2020 23:00:20

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-29T19:00:03', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '3426e09c-35b4-486d-bfd7-8857cb8fdcf2'	System	29 Sep 2020 23:00:20
User entered 'None (1)'	System	29 Sep 2020 23:00:20

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-29T19:00:18', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '3426e09c-35b4-486d-bfd7-8857cb8fdcf2'	System	29 Sep 2020 23:00:20
User entered '29 Sep 2020 19:00'	System	29 Sep 2020 23:00:20

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	28 Sep 2020 16:54:55
User entered 'Day 3'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-30T21:16:45', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'bf4f1f8b-d379-4743-a295-6c1cf9aaffcb'	System	01 Oct 2020 01:21:49
User entered 'Does not interfere with activity (2)'	System	01 Oct 2020 01:21:49

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-30T21:16:51', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'bf4f1f8b-d379-4743-a295-6c1cf9aaffcb'	System	01 Oct 2020 01:21:49
User entered 'Yes (Y)'	System	01 Oct 2020 01:21:49

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-30T21:18:36', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'bf4f1f8b-d379-4743-a295-6c1cf9aaffcb' User entered '9'	System	01 Oct 2020 01:21:49
	System	01 Oct 2020 01:21:49

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-30T21:19:46', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'bf4f1f8b-d379-4743-a295-6c1cf9aaffcb'	System	01 Oct 2020 01:21:49
User entered 'Yes (Y)'	System	01 Oct 2020 01:21:49

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-30T21:19:57', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'bf4f1f8b-d379-4743-a295-6c1cf9aaffcb'	System	01 Oct 2020 01:21:49
User entered '3'	System	01 Oct 2020 01:21:49

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-30T21:21:23', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'bf4f1f8b-d379-4743-a295-6c1cf9aaffcb'	System	01 Oct 2020 01:21:49
User entered 'None (1)'	System	01 Oct 2020 01:21:49

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-30T21:21:44', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'bf4f1f8b-d379-4743-a295-6c1cf9aaffcb'	System	01 Oct 2020 01:21:49
User entered '30 Sep 2020 21:21'	System	01 Oct 2020 01:21:49

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	28 Sep 2020 16:54:55
User entered 'Day 4'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-01T20:07:48', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '8745af65-d1f3-4619-b235-70750c83425c'	System	02 Oct 2020 00:09:15
User entered 'Does not interfere with activity (2)'	System	02 Oct 2020 00:09:15

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-01T20:08:24', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '8745af65-d1f3-4619-b235-70750c83425c'	System	02 Oct 2020 00:09:15
User entered 'No (N)'	System	02 Oct 2020 00:09:15

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

Is there any SWELLING/HARDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-01T20:08:37', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '8745af65-d1f3-4619-b235-70750c83425c'	System	02 Oct 2020 00:09:15
User entered 'No (N)'	System	02 Oct 2020 00:09:15

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-01T20:09:06', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '8745af65-d1f3-4619-b235-70750c83425c'	System	02 Oct 2020 00:09:15
User entered 'None (1)'	System	02 Oct 2020 00:09:15

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-01T20:09:11', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '8745af65-d1f3-4619-b235-70750c83425c'	System	02 Oct 2020 00:09:15
User entered '01 Oct 2020 20:09'	System	02 Oct 2020 00:09:15

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	28 Sep 2020 16:54:55
User entered 'Day 5'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-02T22:50:47', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'e120b5f6-873e-473f-a947-298cd0d46284'	System	03 Oct 2020 02:51:15
User entered 'None (1)'	System	03 Oct 2020 02:51:15

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-02T22:50:50', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'e120b5f6-873e-473f-a947-298cd0d46284'	System	03 Oct 2020 02:51:15
User entered 'No (N)'	System	03 Oct 2020 02:51:15

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-02T22:50:53', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'e120b5f6-873e-473f-a947-298cd0d46284'	System	03 Oct 2020 02:51:15
User entered 'No (N)'	System	03 Oct 2020 02:51:15

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-02T22:51:05', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'e120b5f6-873e-473f-a947-298cd0d46284'	System	03 Oct 2020 02:51:15
User entered 'None (1)'	System	03 Oct 2020 02:51:15

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-02T22:51:12', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'e120b5f6-873e-473f-a947-298cd0d46284'	System	03 Oct 2020 02:51:15
User entered '02 Oct 2020 22:51'	System	03 Oct 2020 02:51:15

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	28 Sep 2020 16:54:55
User entered 'Day 6'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-03T20:09:51', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '6a63a423-2836-492f-b732-17d61ca8d068'	System	04 Oct 2020 00:11:00
User entered 'None (1)'	System	04 Oct 2020 00:11:00

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-03T20:09:55', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '6a63a423-2836-492f-b732-17d61ca8d068'	System	04 Oct 2020 00:11:00
User entered 'No (N)'	System	04 Oct 2020 00:11:00

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-03T20:09:57', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '6a63a423-2836-492f-b732-17d61ca8d068'	System	04 Oct 2020 00:11:00
User entered 'No (N)'	System	04 Oct 2020 00:11:00

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-03T20:10:36', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '6a63a423-2836-492f-b732-17d61ca8d068'	System	04 Oct 2020 00:11:00
User entered 'None (1)'	System	04 Oct 2020 00:11:00

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-03T20:10:56', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '6a63a423-2836-492f-b732-17d61ca8d068'	System	04 Oct 2020 00:11:00
User entered '03 Oct 2020 20:10'	System	04 Oct 2020 00:11:00

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	28 Sep 2020 16:54:55
User entered 'Day 7'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-04T18:52:14', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ca72a82a-071c-4d1f-8d07-b9ea7d4a9d27'	System	04 Oct 2020 22:53:07
User entered 'None (1)'	System	04 Oct 2020 22:53:07

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-04T18:52:37', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ca72a82a-071c-4d1f-8d07-b9ea7d4a9d27'	System	04 Oct 2020 22:53:07
User entered 'No (N)'	System	04 Oct 2020 22:53:07

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

Is there any any SWELLING/HARDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-04T18:52:41', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ca72a82a-071c-4d1f-8d07-b9ea7d4a9d27'	System	04 Oct 2020 22:53:07
User entered 'No (N)'	System	04 Oct 2020 22:53:07

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-04T18:52:54', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ca72a82a-071c-4d1f-8d07-b9ea7d4a9d27'	System	04 Oct 2020 22:53:07
User entered 'None (1)'	System	04 Oct 2020 22:53:07

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-04T18:53:02', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ca72a82a-071c-4d1f-8d07-b9ea7d4a9d27'	System	04 Oct 2020 22:53:07
User entered '04 Oct 2020 18:53'	System	04 Oct 2020 22:53:07

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	28 Sep 2020 16:54:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-28T13:14:36', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '7887371d-bb01-4703-ba89-f8bd2a0a03e9' User entered 'None (0)'	System	28 Sep 2020 17:15:06
	System	28 Sep 2020 17:15:06

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-28T13:14:39', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '7887371d-bb01-4703-ba89-f8bd2a0a03e9' User entered 'None (0)'	System	28 Sep 2020 17:15:06
	System	28 Sep 2020 17:15:06

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-28T13:14:42', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '7887371d-bb01-4703-ba89-f8bd2a0a03e9' User entered 'None (0)'	System	28 Sep 2020 17:15:06
	System	28 Sep 2020 17:15:06

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-28T13:14:45', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '7887371d-bb01-4703-ba89-f8bd2a0a03e9' User entered 'None (0)'	System	28 Sep 2020 17:15:06
	System	28 Sep 2020 17:15:06

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-28T13:14:49', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '7887371d-bb01-4703-ba89-f8bd2a0a03e9' User entered 'None (0)'	System	28 Sep 2020 17:15:06
	System	28 Sep 2020 17:15:06

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-28T13:14:52', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '7887371d-bb01-4703-ba89-f8bd2a0a03e9' User entered 'None (0)'	System	28 Sep 2020 17:15:06
	System	28 Sep 2020 17:15:06

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-28T13:14:56', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '7887371d-bb01-4703-ba89-f8bd2a0a03e9' User entered 'No (N)'	System	28 Sep 2020 17:15:06
	System	28 Sep 2020 17:15:06

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-28T13:15:01', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '7887371d-bb01-4703-ba89-f8bd2a0a03e9' User entered '28 Sep 2020 13:15'	System	28 Sep 2020 17:15:06
	System	28 Sep 2020 17:15:06

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '28 Sep 2020 13:01'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '28 Sep 2020 15:31'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	28 Sep 2020 16:54:55
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-28T20:17:45', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '0bdcbeeb-aa77-4feb-a087-4adacee34c9d'	System	29 Sep 2020 00:18:20
User entered 'None (0)'	System	29 Sep 2020 00:18:20

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-28T20:17:48', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '0bdcbeeb-aa77-4feb-a087-4adacee34c9d'	System	29 Sep 2020 00:18:20
User entered 'None (0)'	System	29 Sep 2020 00:18:20

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-28T20:17:56', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '0bdcbeeb-aa77-4feb-a087-4adacee34c9d'	System	29 Sep 2020 00:18:20
User entered 'None (0)'	System	29 Sep 2020 00:18:20

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-28T20:18:01', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '0bdcbeeb-aa77-4feb-a087-4adacee34c9d'	System	29 Sep 2020 00:18:20
User entered 'None (0)'	System	29 Sep 2020 00:18:20

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-28T20:18:03', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '0bdcbeeb-aa77-4feb-a087-4adacee34c9d'	System	29 Sep 2020 00:18:20
User entered 'None (0)'	System	29 Sep 2020 00:18:20

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-28T20:18:06', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '0bdcbeeb-aa77-4feb-a087-4adacee34c9d'	System	29 Sep 2020 00:18:20
User entered 'None (0)'	System	29 Sep 2020 00:18:20

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-28T20:18:11', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '0bdcbeeb-aa77-4feb-a087-4adacee34c9d'	System	29 Sep 2020 00:18:20
User entered 'No (N)'	System	29 Sep 2020 00:18:20

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-28T20:18:15', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '0bdcbeeb-aa77-4feb-a087-4adacee34c9d'	System	29 Sep 2020 00:18:20
User entered '28 Sep 2020 20:18'	System	29 Sep 2020 00:18:20

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '28 Sep 2020 16:26'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	28 Sep 2020 16:54:55
User entered 'Day 2'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-29T19:00:28', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'f5ef90a2-adb5-419f-b503-9924e7c8e47e'	System	29 Sep 2020 23:01:23
User entered 'No interference with activity (1)'	System	29 Sep 2020 23:01:23

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-29T19:00:37', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'f5ef90a2-adb5-419f-b503-9924e7c8e47e'	System	29 Sep 2020 23:01:23
User entered 'No interference with activity (1)'	System	29 Sep 2020 23:01:23

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-29T19:00:43', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'f5ef90a2-adb5-419f-b503-9924e7c8e47e' User entered 'None (0)'	System	29 Sep 2020 23:01:23
	System	29 Sep 2020 23:01:23

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-29T19:00:50', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'f5ef90a2-adb5-419f-b503-9924e7c8e47e' User entered 'None (0)'	System	29 Sep 2020 23:01:23
	System	29 Sep 2020 23:01:23

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-29T19:00:58', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'f5ef90a2-adb5-419f-b503-9924e7c8e47e'	System	29 Sep 2020 23:01:23
User entered 'None (0)'	System	29 Sep 2020 23:01:23

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-29T19:01:02', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'f5ef90a2-adb5-419f-b503-9924e7c8e47e'	System	29 Sep 2020 23:01:23
User entered 'None (0)'	System	29 Sep 2020 23:01:23

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-29T19:01:07', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'f5ef90a2-adb5-419f-b503-9924e7c8e47e'	System	29 Sep 2020 23:01:23
User entered 'No (N)'	System	29 Sep 2020 23:01:23

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-29T19:01:19', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'f5ef90a2-adb5-419f-b503-9924e7c8e47e' User entered '29 Sep 2020 19:01'	System	29 Sep 2020 23:01:23
	System	29 Sep 2020 23:01:23

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	28 Sep 2020 16:54:55
User entered 'Day 3'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-30T21:21:56', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'a21f1ffb-7fa5-4a88-83e5-f44af4ea7c6d'	System	01 Oct 2020 01:24:22
User entered 'No interference with activity (1)'	System	01 Oct 2020 01:24:22

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-30T21:22:23', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'a21f1ffb-7fa5-4a88-83e5-f44af4ea7c6d'	System	01 Oct 2020 01:24:22
User entered 'None (0)'	System	01 Oct 2020 01:24:22

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-30T21:22:34', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'a21f1ffb-7fa5-4a88-83e5-f44af4ea7c6d'	System	01 Oct 2020 01:24:22
User entered 'None (0)'	System	01 Oct 2020 01:24:22

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-30T21:23:46', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'a21f1ffb-7fa5-4a88-83e5-f44af4ea7c6d'	System	01 Oct 2020 01:24:22
User entered 'None (0)'	System	01 Oct 2020 01:24:22

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-30T21:23:49', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'a21f1ffb-7fa5-4a88-83e5-f44af4ea7c6d'	System	01 Oct 2020 01:24:22
User entered 'None (0)'	System	01 Oct 2020 01:24:22

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-30T21:23:57', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'a21f1ffb-7fa5-4a88-83e5-f44af4ea7c6d'	System	01 Oct 2020 01:24:22
User entered 'None (0)'	System	01 Oct 2020 01:24:22

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-30T21:24:01', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'a21f1ffb-7fa5-4a88-83e5-f44af4ea7c6d'	System	01 Oct 2020 01:24:22
User entered 'No (N)'	System	01 Oct 2020 01:24:22

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-09-30T21:24:19', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'a21f1ffb-7fa5-4a88-83e5-f44af4ea7c6d'	System	01 Oct 2020 01:24:22
User entered '30 Sep 2020 21:24'	System	01 Oct 2020 01:24:22

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	28 Sep 2020 16:54:55
User entered 'Day 4'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-01T20:09:16', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '5d9bebf4-3847-4eae-88e0-a7602abfe4c1'	System	02 Oct 2020 00:09:40
User entered 'None (0)'	System	02 Oct 2020 00:09:40

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-01T20:09:18', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '5d9bebf4-3847-4eae-88e0-a7602abfe4c1'	System	02 Oct 2020 00:09:40
User entered 'None (0)'	System	02 Oct 2020 00:09:40

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-01T20:09:21', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '5d9bebf4-3847-4eae-88e0-a7602abfe4c1'	System	02 Oct 2020 00:09:40
User entered 'None (0)'	System	02 Oct 2020 00:09:40

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-01T20:09:24', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '5d9bebf4-3847-4eae-88e0-a7602abfe4c1'	System	02 Oct 2020 00:09:40
User entered 'None (0)'	System	02 Oct 2020 00:09:40

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-01T20:09:27', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '5d9bebf4-3847-4eae-88e0-a7602abfe4c1'	System	02 Oct 2020 00:09:40
User entered 'None (0)'	System	02 Oct 2020 00:09:40

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-01T20:09:29', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '5d9bebf4-3847-4eae-88e0-a7602abfe4c1'	System	02 Oct 2020 00:09:40
User entered 'None (0)'	System	02 Oct 2020 00:09:40

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-01T20:09:32', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '5d9bebf4-3847-4eae-88e0-a7602abfe4c1'	System	02 Oct 2020 00:09:40
User entered 'No (N)'	System	02 Oct 2020 00:09:40

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-01T20:09:36', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '5d9bebf4-3847-4eae-88e0-a7602abfe4c1'	System	02 Oct 2020 00:09:40
User entered '01 Oct 2020 20:09'	System	02 Oct 2020 00:09:40

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	28 Sep 2020 16:54:55
User entered 'Day 5'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-02T22:51:19', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '341d3835-535b-4d19-86be-1aee6ac911aa'	System	03 Oct 2020 02:51:46
User entered 'None (0)'	System	03 Oct 2020 02:51:46

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-02T22:51:21', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '341d3835-535b-4d19-86be-1aee6ac911aa'	System	03 Oct 2020 02:51:46
User entered 'None (0)'	System	03 Oct 2020 02:51:46

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-02T22:51:23', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '341d3835-535b-4d19-86be-1aee6ac911aa'	System	03 Oct 2020 02:51:46
User entered 'None (0)'	System	03 Oct 2020 02:51:46

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-02T22:51:26', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '341d3835-535b-4d19-86be-1aee6ac911aa'	System	03 Oct 2020 02:51:46
User entered 'None (0)'	System	03 Oct 2020 02:51:46

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-02T22:51:29', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '341d3835-535b-4d19-86be-1aee6ac911aa'	System	03 Oct 2020 02:51:46
User entered 'None (0)'	System	03 Oct 2020 02:51:46

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-02T22:51:31', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '341d3835-535b-4d19-86be-1aee6ac911aa'	System	03 Oct 2020 02:51:46
User entered 'None (0)'	System	03 Oct 2020 02:51:46

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-02T22:51:34', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '341d3835-535b-4d19-86be-1aee6ac911aa'	System	03 Oct 2020 02:51:46
User entered 'No (N)'	System	03 Oct 2020 02:51:46

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-02T22:51:40', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '341d3835-535b-4d19-86be-1aee6ac911aa'	System	03 Oct 2020 02:51:46
User entered '02 Oct 2020 22:51'	System	03 Oct 2020 02:51:46

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	28 Sep 2020 16:54:55
User entered 'Day 6'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-03T20:11:14', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ebfbf0e3-7d23-411d-8974-39ac508fd553'	System	04 Oct 2020 00:12:01
User entered 'No interference with activity (1)'	System	04 Oct 2020 00:12:01

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-03T20:11:25', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ebfbf0e3-7d23-411d-8974-39ac508fd553'	System	04 Oct 2020 00:12:01
User entered 'No interference with activity (1)'	System	04 Oct 2020 00:12:01

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-03T20:11:28', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ebfbf0e3-7d23-411d-8974-39ac508fd553'	System	04 Oct 2020 00:12:01
User entered 'None (0)'	System	04 Oct 2020 00:12:01

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-03T20:11:31', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ebfbf0e3-7d23-411d-8974-39ac508fd553'	System	04 Oct 2020 00:12:01
User entered 'None (0)'	System	04 Oct 2020 00:12:01

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-03T20:11:34', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ebfbf0e3-7d23-411d-8974-39ac508fd553'	System	04 Oct 2020 00:12:01
User entered 'None (0)'	System	04 Oct 2020 00:12:01

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-03T20:11:37', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ebfbf0e3-7d23-411d-8974-39ac508fd553'	System	04 Oct 2020 00:12:01
User entered 'None (0)'	System	04 Oct 2020 00:12:01

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-03T20:11:40', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ebfbf0e3-7d23-411d-8974-39ac508fd553'	System	04 Oct 2020 00:12:01
User entered 'No (N)'	System	04 Oct 2020 00:12:01

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-03T20:11:49', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ebfbf0e3-7d23-411d-8974-39ac508fd553'	System	04 Oct 2020 00:12:01
User entered '03 Oct 2020 20:11'	System	04 Oct 2020 00:12:01

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	28 Sep 2020 16:54:55
User entered 'Day 7'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-04T18:53:13', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '1c82a119-3c28-4895-8bc5-28d9ab913f8a' User entered 'None (0)'	System	04 Oct 2020 22:54:27
	System	04 Oct 2020 22:54:27

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-04T18:53:29', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '1c82a119-3c28-4895-8bc5-28d9ab913f8a' User entered 'None (0)'	System	04 Oct 2020 22:54:27
	System	04 Oct 2020 22:54:27

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-04T18:53:34', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '1c82a119-3c28-4895-8bc5-28d9ab913f8a'	System	04 Oct 2020 22:54:27
User entered 'None (0)'	System	04 Oct 2020 22:54:27

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-04T18:53:44', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '1c82a119-3c28-4895-8bc5-28d9ab913f8a' User entered 'None (0)'	System	04 Oct 2020 22:54:27
	System	04 Oct 2020 22:54:27

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-04T18:53:47', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '1c82a119-3c28-4895-8bc5-28d9ab913f8a'	System	04 Oct 2020 22:54:27
User entered 'None (0)'	System	04 Oct 2020 22:54:27

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-04T18:53:49', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '1c82a119-3c28-4895-8bc5-28d9ab913f8a'	System	04 Oct 2020 22:54:27
User entered 'None (0)'	System	04 Oct 2020 22:54:27

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-04T18:54:12', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '1c82a119-3c28-4895-8bc5-28d9ab913f8a'	System	04 Oct 2020 22:54:27
User entered 'No (N)'	System	04 Oct 2020 22:54:27

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-04T18:54:23', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '1c82a119-3c28-4895-8bc5-28d9ab913f8a'	System	04 Oct 2020 22:54:27
User entered '04 Oct 2020 18:54'	System	04 Oct 2020 22:54:27

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 16:54:55

US3602004

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	04 Oct 2020 00:12:01
User entered 'Day 8'	System	04 Oct 2020 00:12:01

US3602004

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:08:05

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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-05T21:26:50', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'fb008a86-22b1-4c51-9265-0b1ccffe6a8a'	System	06 Oct 2020 01:27:03
User entered 'No (N)'	System	06 Oct 2020 01:27:03

US3602004

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:08:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-10-05T21:26:58', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'fb008a86-22b1-4c51-9265-0b1ccffe6a8a'	System	06 Oct 2020 01:27:03
User entered '05 Oct 2020 21:26'	System	06 Oct 2020 01:27:03

US3602004

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 00:12:01

US3602004

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 00:12:01

US3602004

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:00:22

US3602004

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	27 Mar 2021 20:18:50
Signature has been broken.	(b) (4), (b) (6)	26 Mar 2021 16:47:26
User entered '5 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 16:47:26
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '8 Oct 2020'	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 14:00:22

US3602004

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:00:22

US3602004

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:00:22

US3602004

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:00:13

US3602004

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'I'	System	09 Oct 2020 14:00:13

US3602004

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 15:33:15

US3602004

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	27 Mar 2021 20:18:50
Signature has been broken.	(b) (4), (b) (6)	26 Mar 2021 16:49:34
User entered '12 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 16:49:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '13 Oct 2020'	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 15:33:15

US3602004

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 15:33:15

US3602004

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 15:33:15

US3602004

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 15:33:21

US3602004

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'I'	System	26 Oct 2020 15:33:21

US3602004

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 15:33:32

US3602004

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 15:33:32

US3602004

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 15:33:32

US3602004

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 15:33:32

US3602004

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 15:33:38

US3602004

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'I'	System	26 Oct 2020 15:33:38

US3602004

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 03:40:38

US3602004

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '26 Oct 2020'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 03:40:38

US3602004

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 03:40:38

US3602004

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'VISIT3'	System	27 Oct 2020 03:40:38

US3602004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 03:41:47

US3602004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '26 Oct 2020'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 03:41:47

US3602004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '13:55'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 03:41:47

US3602004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered '26 Oct 2020 13:55'	System	27 Oct 2020 03:41:47

US3602004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	27 Oct 2020 03:41:47

US3602004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 03:41:47

US3602004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'Temporal'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 03:41:47

US3602004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '68'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 03:41:47

US3602004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'bpm'	System	27 Oct 2020 03:41:47

US3602004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '16'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 03:41:47

US3602004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'breaths/min'	System	27 Oct 2020 03:41:47

US3602004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '121'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 03:41:47

US3602004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'mmHg'	System	27 Oct 2020 03:41:47

US3602004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '66'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 03:41:47

US3602004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'mmHg'	System	27 Oct 2020 03:41:47

US3602004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50

US3602004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50

US3602004

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:08:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 03:40:47

US3602004

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:08:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '26 Oct 2020'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 03:40:47

US3602004

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 03:41:58

US3602004

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '26 Oct 2020'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 03:41:58

US3602004

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered '13:55'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 03:41:58

US3602004

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered '26 Oct 2020 13:55'	System	27 Oct 2020 03:41:58

US3602004

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:38:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 03:40:58

US3602004

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'I'	System	27 Oct 2020 03:40:58

US3602004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	02 Sep 2020 18:22:59
User entered 'Day 64'	System	02 Sep 2020 18:22:59

US3602004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-11-02T19:30:44', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '0e3f9545-e27b-4399-8e02-3f6a18fbadda'	System	03 Nov 2020 00:31:27
User entered 'No (N)'	System	03 Nov 2020 00:31:27

US3602004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Have you been exposed to someone with 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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-11-02T19:30:57', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '0e3f9545-e27b-4399-8e02-3f6a18fbadda'	System	03 Nov 2020 00:31:27
User entered 'No (N)'	System	03 Nov 2020 00:31:27

US3602004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-11-02T19:31:22', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '0e3f9545-e27b-4399-8e02-3f6a18fbadda'	System	03 Nov 2020 00:31:27
User entered '02 Nov 2020 19:31:22'	System	03 Nov 2020 00:31:27

US3602004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	02 Sep 2020 18:22:59
User entered '02 Nov 2020 00:01'	System	02 Sep 2020 18:22:59

US3602004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	02 Sep 2020 18:22:59
User entered '06 Nov 2020 23:59'	System	02 Sep 2020 18:22:59

US3602004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	02 Sep 2020 18:22:59
User entered 'Day 71'	System	02 Sep 2020 18:22:59

US3602004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-11-09T21:29:16', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '36b2ffd7-cf90-47bc-8c44-18d63098d0dd'	System	10 Nov 2020 02:29:38
User entered 'No (N)'	System	10 Nov 2020 02:29:38

US3602004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Have you been exposed to someone with 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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-11-09T21:29:28', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '36b2ffd7-cf90-47bc-8c44-18d63098d0dd'	System	10 Nov 2020 02:29:38
User entered 'No (N)'	System	10 Nov 2020 02:29:38

US3602004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-11-09T21:29:34', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '36b2ffd7-cf90-47bc-8c44-18d63098d0dd'	System	10 Nov 2020 02:29:38
User entered '09 Nov 2020 21:29:34'	System	10 Nov 2020 02:29:38

US3602004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	02 Sep 2020 18:22:59
User entered '09 Nov 2020 00:01'	System	02 Sep 2020 18:22:59

US3602004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	02 Sep 2020 18:22:59
User entered '13 Nov 2020 23:59'	System	02 Sep 2020 18:22:59

US3602004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	02 Sep 2020 18:22:59
User entered 'Day 78'	System	02 Sep 2020 18:22:59

US3602004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-11-16T20:36:30', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'b6d5652a-612f-48f2-bd74-4582c20ab709'	System	17 Nov 2020 01:37:01
User entered 'No (N)'	System	17 Nov 2020 01:37:01

US3602004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Have you been exposed to someone with 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 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-11-16T20:36:43', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'b6d5652a-612f-48f2-bd74-4582c20ab709'	System	17 Nov 2020 01:37:01
User entered 'No (N)'	System	17 Nov 2020 01:37:01

US3602004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-11-16T20:36:58', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'b6d5652a-612f-48f2-bd74-4582c20ab709'	System	17 Nov 2020 01:37:01
User entered '16 Nov 2020 20:36:58'	System	17 Nov 2020 01:37:01

US3602004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	02 Sep 2020 18:22:59
User entered '16 Nov 2020 00:01'	System	02 Sep 2020 18:22:59

US3602004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:02
Data entry locked.	System	02 Sep 2020 18:22:59
User entered '20 Nov 2020 23:59'	System	02 Sep 2020 18:22:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[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 (b5142763cae9e7cb)', Time: '2020-11-23T18:07:07', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '57067a94-7e9f-4294-97da-67694b7a49c2'	System	23 Nov 2020 23:07:18
User entered 'No (N)'	System	23 Nov 2020 23:07:18

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Have you been exposed to someone with 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 (b5142763cae9e7cb)', Time: '2020-11-23T18:07:11', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '57067a94-7e9f-4294-97da-67694b7a49c2'	System	23 Nov 2020 23:07:18
User entered 'No (N)'	System	23 Nov 2020 23:07:18

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-11-23T18:07:15', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '57067a94-7e9f-4294-97da-67694b7a49c2'	System	23 Nov 2020 23:07:18
User entered '23 Nov 2020 18:07:15'	System	23 Nov 2020 23:07:18

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[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 (b5142763cae9e7cb)', Time: '2020-11-30T17:56:55', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'a477e944-0ee7-4c40-97a3-3d23daa750e9'	System	30 Nov 2020 22:57:12
User entered 'No (N)'	System	30 Nov 2020 22:57:12

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Have you been exposed to someone with 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 (b5142763cae9e7cb)', Time: '2020-11-30T17:57:02', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'a477e944-0ee7-4c40-97a3-3d23daa750e9'	System	30 Nov 2020 22:57:12
User entered 'No (N)'	System	30 Nov 2020 22:57:12

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-11-30T17:57:07', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'a477e944-0ee7-4c40-97a3-3d23daa750e9' User entered '30 Nov 2020 17:57:07'	System	30 Nov 2020 22:57:12
	System	30 Nov 2020 22:57:12

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[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 (b5142763cae9e7cb)', Time: '2020-12-06T13:38:31', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ea8b68e9-524e-496c-9ad7-71188e752819'	System	06 Dec 2020 18:39:50
User entered 'Yes (Y)'	System	06 Dec 2020 18:39:50

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Have you been exposed to someone with 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 (b5142763cae9e7cb)', Time: '2020-12-06T13:38:37', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ea8b68e9-524e-496c-9ad7-71188e752819'	System	06 Dec 2020 18:39:50
User entered 'No (N)'	System	06 Dec 2020 18:39:50

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[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 (b5142763cae9e7cb)', Time: '2020-12-06T13:38:53', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ea8b68e9-524e-496c-9ad7-71188e752819'	System	06 Dec 2020 18:39:50
User entered 'Yes (Y)'	System	06 Dec 2020 18:39:50

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-12-06T13:39:08', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ea8b68e9-524e-496c-9ad7-71188e752819'	System	06 Dec 2020 18:39:50
User entered '0'	System	06 Dec 2020 18:39:50

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-12-06T13:39:08', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ea8b68e9-524e-496c-9ad7-71188e752819'	System	06 Dec 2020 18:39:50
User entered '0'	System	06 Dec 2020 18:39:50

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-12-06T13:39:08', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ea8b68e9-524e-496c-9ad7-71188e752819'	System	06 Dec 2020 18:39:50
User entered '0'	System	06 Dec 2020 18:39:50

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-12-06T13:39:08', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ea8b68e9-524e-496c-9ad7-71188e752819'	System	06 Dec 2020 18:39:50
User entered '0'	System	06 Dec 2020 18:39:50

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-12-06T13:39:08', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ea8b68e9-524e-496c-9ad7-71188e752819'	System	06 Dec 2020 18:39:50
User entered '0'	System	06 Dec 2020 18:39:50

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-12-06T13:39:08', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ea8b68e9-524e-496c-9ad7-71188e752819'	System	06 Dec 2020 18:39:50
User entered '0'	System	06 Dec 2020 18:39:50

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-12-06T13:39:08', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ea8b68e9-524e-496c-9ad7-71188e752819'	System	06 Dec 2020 18:39:50
User entered '0'	System	06 Dec 2020 18:39:50

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-12-06T13:39:08', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ea8b68e9-524e-496c-9ad7-71188e752819'	System	06 Dec 2020 18:39:50
User entered '0'	System	06 Dec 2020 18:39:50

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-12-06T13:39:08', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ea8b68e9-524e-496c-9ad7-71188e752819'	System	06 Dec 2020 18:39:50
User entered '1'	System	06 Dec 2020 18:39:50

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-12-06T13:39:08', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ea8b68e9-524e-496c-9ad7-71188e752819'	System	06 Dec 2020 18:39:50
User entered '0'	System	06 Dec 2020 18:39:50

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-12-06T13:39:08', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ea8b68e9-524e-496c-9ad7-71188e752819'	System	06 Dec 2020 18:39:50
User entered '0'	System	06 Dec 2020 18:39:50

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-12-06T13:39:08', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ea8b68e9-524e-496c-9ad7-71188e752819'	System	06 Dec 2020 18:39:50
User entered '0'	System	06 Dec 2020 18:39:50

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-12-06T13:39:08', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ea8b68e9-524e-496c-9ad7-71188e752819'	System	06 Dec 2020 18:39:50
User entered '1'	System	06 Dec 2020 18:39:50

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-12-06T13:39:08', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ea8b68e9-524e-496c-9ad7-71188e752819'	System	06 Dec 2020 18:39:50
User entered '1'	System	06 Dec 2020 18:39:50

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-12-06T13:39:08', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ea8b68e9-524e-496c-9ad7-71188e752819'	System	06 Dec 2020 18:39:50
User entered '0'	System	06 Dec 2020 18:39:50

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-12-06T13:39:08', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ea8b68e9-524e-496c-9ad7-71188e752819'	System	06 Dec 2020 18:39:50
User entered '0'	System	06 Dec 2020 18:39:50

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-12-06T13:39:08', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ea8b68e9-524e-496c-9ad7-71188e752819'	System	06 Dec 2020 18:39:50
User entered '0'	System	06 Dec 2020 18:39:50

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-12-06T13:39:18', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ea8b68e9-524e-496c-9ad7-71188e752819'	System	06 Dec 2020 18:39:50
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Dec 2020 18:39:50

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[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 (b5142763cae9e7cb)', Time: '2020-12-06T13:39:31', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ea8b68e9-524e-496c-9ad7-71188e752819'	System	06 Dec 2020 18:39:50
User entered 'Yes (Y)'	System	06 Dec 2020 18:39:50

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-12-06T13:39:36', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ea8b68e9-524e-496c-9ad7-71188e752819'	System	06 Dec 2020 18:39:50
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Dec 2020 18:39:50

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-12-06T13:39:42', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ea8b68e9-524e-496c-9ad7-71188e752819'	System	06 Dec 2020 18:39:50
User entered '06 Dec 2020 13:39:42'	System	06 Dec 2020 18:39:50

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[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 (b5142763cae9e7cb)', Time: '2020-12-14T20:30:48', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '570c3824-de6b-4e5c-9d2c-7c3ef2de9d93'	System	15 Dec 2020 01:31:11
User entered 'No (N)'	System	15 Dec 2020 01:31:11

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Have you been exposed to someone with 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 (b5142763cae9e7cb)', Time: '2020-12-14T20:30:56', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '570c3824-de6b-4e5c-9d2c-7c3ef2de9d93'	System	15 Dec 2020 01:31:11
User entered 'No (N)'	System	15 Dec 2020 01:31:11

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-12-14T20:31:06', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '570c3824-de6b-4e5c-9d2c-7c3ef2de9d93'	System	15 Dec 2020 01:31:11
User entered '14 Dec 2020 20:31:06'	System	15 Dec 2020 01:31:11

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[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 (b5142763cae9e7cb)', Time: '2020-12-21T18:05:08', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'e7c044e6-9445-4536-bbab-ad45b6e9c6e0'	System	21 Dec 2020 23:06:24
User entered 'No (N)'	System	21 Dec 2020 23:06:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Have you been exposed to someone with 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 (b5142763cae9e7cb)', Time: '2020-12-21T18:06:16', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'e7c044e6-9445-4536-bbab-ad45b6e9c6e0'	System	21 Dec 2020 23:06:24
User entered 'No (N)'	System	21 Dec 2020 23:06:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-12-21T18:06:21', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'e7c044e6-9445-4536-bbab-ad45b6e9c6e0' User entered '21 Dec 2020 18:06:21'	System	21 Dec 2020 23:06:24
	System	21 Dec 2020 23:06:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[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 (b5142763cae9e7cb)', Time: '2020-12-27T14:16:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'c1dfb5fe-586b-4633-8838-90518dfc65b6'	System	27 Dec 2020 19:16:15
User entered 'No (N)'	System	27 Dec 2020 19:16:15

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Have you been exposed to someone with 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 (b5142763cae9e7cb)', Time: '2020-12-27T14:16:06', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'c1dfb5fe-586b-4633-8838-90518dfc65b6'	System	27 Dec 2020 19:16:15
User entered 'No (N)'	System	27 Dec 2020 19:16:15

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2020-12-27T14:16:10', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'c1dfb5fe-586b-4633-8838-90518dfc65b6'	System	27 Dec 2020 19:16:15
User entered '27 Dec 2020 14:16:10'	System	27 Dec 2020 19:16:15

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[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 (b5142763cae9e7cb)', Time: '2021-01-01T22:11:13', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'b44634b2-3a46-4d19-9c7d-267c8931bee7'	System	02 Jan 2021 03:11:30
User entered 'No (N)'	System	02 Jan 2021 03:11:30

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Have you been exposed to someone with 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 (b5142763cae9e7cb)', Time: '2021-01-01T22:11:20', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'b44634b2-3a46-4d19-9c7d-267c8931bee7'	System	02 Jan 2021 03:11:30
User entered 'No (N)'	System	02 Jan 2021 03:11:30

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2021-01-01T22:11:28', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'b44634b2-3a46-4d19-9c7d-267c8931bee7'	System	02 Jan 2021 03:11:30
User entered '01 Jan 2021 22:11:28'	System	02 Jan 2021 03:11:30

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[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 (b5142763cae9e7cb)', Time: '2021-01-11T19:11:35', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ac23603d-b5a3-42f7-8983-c959bbb2302a'	System	12 Jan 2021 00:11:48
User entered 'No (N)'	System	12 Jan 2021 00:11:48

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Have you been exposed to someone with 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 (b5142763cae9e7cb)', Time: '2021-01-11T19:11:41', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ac23603d-b5a3-42f7-8983-c959bbb2302a'	System	12 Jan 2021 00:11:48
User entered 'No (N)'	System	12 Jan 2021 00:11:48

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2021-01-11T19:11:46', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ac23603d-b5a3-42f7-8983-c959bbb2302a'	System	12 Jan 2021 00:11:48
User entered '11 Jan 2021 19:11:46'	System	12 Jan 2021 00:11:48

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[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 (b5142763cae9e7cb)', Time: '2021-01-18T06:58:35', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'a8b495dc-20d6-46c8-b50d-568775704c70'	System	18 Jan 2021 11:58:51
User entered 'No (N)'	System	18 Jan 2021 11:58:51

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Have you been exposed to someone with 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 (b5142763cae9e7cb)', Time: '2021-01-18T06:58:41', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'a8b495dc-20d6-46c8-b50d-568775704c70'	System	18 Jan 2021 11:58:51
User entered 'No (N)'	System	18 Jan 2021 11:58:51

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2021-01-18T06:58:48', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'a8b495dc-20d6-46c8-b50d-568775704c70'	System	18 Jan 2021 11:58:51
User entered '18 Jan 2021 06:58:48'	System	18 Jan 2021 11:58:51

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[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 (b5142763cae9e7cb)', Time: '2021-01-25T18:51:36', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '994cc89b-ea6e-4d73-a1b0-8a8070097930'	System	25 Jan 2021 23:51:44
User entered 'No (N)'	System	25 Jan 2021 23:51:44

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Have you been exposed to someone with 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 (b5142763cae9e7cb)', Time: '2021-01-25T18:51:39', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '994cc89b-ea6e-4d73-a1b0-8a8070097930'	System	25 Jan 2021 23:51:44
User entered 'No (N)'	System	25 Jan 2021 23:51:44

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2021-01-25T18:51:43', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '994cc89b-ea6e-4d73-a1b0-8a8070097930' User entered '25 Jan 2021 18:51:43'	System	25 Jan 2021 23:51:44
	System	25 Jan 2021 23:51:44

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[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 (b5142763cae9e7cb)', Time: '2021-01-29T07:16:27', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '35b1de60-bb2e-40eb-ad9a-7da92c235d53'	System	29 Jan 2021 12:16:41
User entered 'No (N)'	System	29 Jan 2021 12:16:41

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Have you been exposed to someone with 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 (b5142763cae9e7cb)', Time: '2021-01-29T07:16:35', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '35b1de60-bb2e-40eb-ad9a-7da92c235d53'	System	29 Jan 2021 12:16:41
User entered 'No (N)'	System	29 Jan 2021 12:16:41

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2021-01-29T07:16:40', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '35b1de60-bb2e-40eb-ad9a-7da92c235d53'	System	29 Jan 2021 12:16:41
User entered '29 Jan 2021 07:16:40'	System	29 Jan 2021 12:16:41

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[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 (b5142763cae9e7cb)', Time: '2021-02-08T18:54:04', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '750a1685-4a2a-43ea-9198-38b596273eb5'	System	08 Feb 2021 23:54:18
User entered 'No (N)'	System	08 Feb 2021 23:54:18

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Have you been exposed to someone with 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 (b5142763cae9e7cb)', Time: '2021-02-08T18:54:10', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '750a1685-4a2a-43ea-9198-38b596273eb5'	System	08 Feb 2021 23:54:18
User entered 'No (N)'	System	08 Feb 2021 23:54:18

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2021-02-08T18:54:13', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '750a1685-4a2a-43ea-9198-38b596273eb5' User entered '08 Feb 2021 18:54:13'	System	08 Feb 2021 23:54:18
	System	08 Feb 2021 23:54:18

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[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 (b5142763cae9e7cb)', Time: '2021-02-15T17:04:48', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '935c8ca2-4e9d-4b81-8347-a946ecd5b826'	System	15 Feb 2021 22:05:07
User entered 'No (N)'	System	15 Feb 2021 22:05:07

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Have you been exposed to someone with 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 (b5142763cae9e7cb)', Time: '2021-02-15T17:04:57', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '935c8ca2-4e9d-4b81-8347-a946ecd5b826'	System	15 Feb 2021 22:05:07
User entered 'No (N)'	System	15 Feb 2021 22:05:07

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2021-02-15T17:05:01', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '935c8ca2-4e9d-4b81-8347-a946ecd5b826' User entered '15 Feb 2021 17:05:01'	System	15 Feb 2021 22:05:07
	System	15 Feb 2021 22:05:07

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[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 (b5142763cae9e7cb)', Time: '2021-02-21T16:16:59', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'e538523e-f82a-457b-b9a4-15687844d148'	System	21 Feb 2021 21:17:14
User entered 'No (N)'	System	21 Feb 2021 21:17:14

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Have you been exposed to someone with 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 (b5142763cae9e7cb)', Time: '2021-02-21T16:17:02', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'e538523e-f82a-457b-b9a4-15687844d148'	System	21 Feb 2021 21:17:14
User entered 'No (N)'	System	21 Feb 2021 21:17:14

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2021-02-21T16:17:10', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'e538523e-f82a-457b-b9a4-15687844d148'	System	21 Feb 2021 21:17:14
User entered '21 Feb 2021 16:17:10'	System	21 Feb 2021 21:17:14

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[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 (b5142763cae9e7cb)', Time: '2021-03-01T18:23:38-05:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '46e6a95e-fc52-4c47-b22f-fcff0ea51566'	System	01 Mar 2021 23:23:55
User entered 'No (N)'	System	01 Mar 2021 23:23:55

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Have you been exposed to someone with 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 (b5142763cae9e7cb)', Time: '2021-03-01T18:23:41-05:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '46e6a95e-fc52-4c47-b22f-fcff0ea51566'	System	01 Mar 2021 23:23:55
User entered 'No (N)'	System	01 Mar 2021 23:23:55

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2021-03-01T18:23:46-05:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '46e6a95e-fc52-4c47-b22f-fcff0ea51566'	System	01 Mar 2021 23:23:55
User entered '01 Mar 2021 18:23:46'	System	01 Mar 2021 23:23:55

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[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 (b5142763cae9e7cb)', Time: '2021-03-08T17:34:11-05:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '387bc6b8-7532-451b-b7fd-f689229dfd16'	System	08 Mar 2021 22:34:26
User entered 'No (N)'	System	08 Mar 2021 22:34:26

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Have you been exposed to someone with 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 (b5142763cae9e7cb)', Time: '2021-03-08T17:34:19-05:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '387bc6b8-7532-451b-b7fd-f689229dfd16'	System	08 Mar 2021 22:34:26
User entered 'No (N)'	System	08 Mar 2021 22:34:26

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2021-03-08T17:34:24-05:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '387bc6b8-7532-451b-b7fd-f689229dfd16'	System	08 Mar 2021 22:34:26
User entered '08 Mar 2021 17:34:24'	System	08 Mar 2021 22:34:26

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[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 (b5142763cae9e7cb)', Time: '2021-03-12T20:06:13-05:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'c739a6b7-eee3-46b8-b02e-cb88f46c5bd4'	System	13 Mar 2021 01:06:45
User entered 'No (N)'	System	13 Mar 2021 01:06:45

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Have you been exposed to someone with 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 (b5142763cae9e7cb)', Time: '2021-03-12T20:06:08-05:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'c739a6b7-eee3-46b8-b02e-cb88f46c5bd4'	System	13 Mar 2021 01:06:45
User entered 'No (N)'	System	13 Mar 2021 01:06:45

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2021-03-12T20:06:42-05:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'c739a6b7-eee3-46b8-b02e-cb88f46c5bd4'	System	13 Mar 2021 01:06:45
User entered '12 Mar 2021 20:06:42'	System	13 Mar 2021 01:06:45

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[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 (b5142763cae9e7cb)', Time: '2021-03-22T18:11:40-04:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ffa5b7ae-08e3-4e42-af2b-1472f40c4b0a' User entered 'No (N)'	System	22 Mar 2021 22:13:11
	System	22 Mar 2021 22:13:11

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Have you been exposed to someone with 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 (b5142763cae9e7cb)', Time: '2021-03-22T18:11:52-04:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ffa5b7ae-08e3-4e42-af2b-1472f40c4b0a'	System	22 Mar 2021 22:13:11
User entered 'No (N)'	System	22 Mar 2021 22:13:11

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2021-03-22T18:11:58-04:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'ffa5b7ae-08e3-4e42-af2b-1472f40c4b0a' User entered '22 Mar 2021 18:11:58'	System	22 Mar 2021 22:13:11

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[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 (b5142763cae9e7cb)', Time: '2021-03-30T06:38:48-04:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '92019ba4-ed58-4b1f-acae-b234ac420084' User entered 'No (N)'	System	30 Mar 2021 10:38:57

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Have you been exposed to someone with 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 (b5142763cae9e7cb)', Time: '2021-03-30T06:38:51-04:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '92019ba4-ed58-4b1f-acae-b234ac420084'	System	30 Mar 2021 10:38:57
User entered 'No (N)'	System	30 Mar 2021 10:38:57

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2021-03-30T06:38:54-04:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '92019ba4-ed58-4b1f-acae-b234ac420084' User entered '30 Mar 2021 06:38:54'	System	30 Mar 2021 10:38:57
	System	30 Mar 2021 10:38:57

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[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 (b5142763cae9e7cb)', Time: '2021-04-05T17:06:00-04:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '99dcdf05-5c4c-4bbd-83f7-05fd81001f7b'	System	05 Apr 2021 21:12:31
User entered 'No (N)'	System	05 Apr 2021 21:12:31

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Have you been exposed to someone with 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 (b5142763cae9e7cb)', Time: '2021-04-05T17:06:03-04:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '99dcdf05-5c4c-4bbd-83f7-05fd81001f7b'	System	05 Apr 2021 21:12:31
User entered 'No (N)'	System	05 Apr 2021 21:12:31

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2021-04-05T17:06:07-04:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '99dcdf05-5c4c-4bbd-83f7-05fd81001f7b'	System	05 Apr 2021 21:12:31
User entered '05 Apr 2021 17:06:07'	System	05 Apr 2021 21:12:31

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[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 (b5142763cae9e7cb)', Time: '2021-04-11T08:02:47-04:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '5e4a9d88-8398-4392-8946-bbd32eb41078'	System	11 Apr 2021 12:02:59
User entered 'No (N)'	System	11 Apr 2021 12:02:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Have you been exposed to someone with 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 (b5142763cae9e7cb)', Time: '2021-04-11T08:02:52-04:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '5e4a9d88-8398-4392-8946-bbd32eb41078'	System	11 Apr 2021 12:02:59
User entered 'No (N)'	System	11 Apr 2021 12:02:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2021-04-11T08:02:55-04:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '5e4a9d88-8398-4392-8946-bbd32eb41078'	System	11 Apr 2021 12:02:59
User entered '11 Apr 2021 08:02:55'	System	11 Apr 2021 12:02:59

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[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 (b5142763cae9e7cb)', Time: '2021-04-19T17:31:27-04:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '934e016b-aa97-48a6-9e26-109f32f4e02b' User entered 'No (N)'	System	19 Apr 2021 21:31:39
	System	19 Apr 2021 21:31:39

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Have you been exposed to someone with 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 (b5142763cae9e7cb)', Time: '2021-04-19T17:31:32-04:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '934e016b-aa97-48a6-9e26-109f32f4e02b'	System	19 Apr 2021 21:31:39
User entered 'No (N)'	System	19 Apr 2021 21:31:39

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2021-04-19T17:31:37-04:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '934e016b-aa97-48a6-9e26-109f32f4e02b'	System	19 Apr 2021 21:31:39
User entered '19 Apr 2021 17:31:37'	System	19 Apr 2021 21:31:39

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[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 (b5142763cae9e7cb)', Time: '2021-04-26T17:18:01-04:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'b7e8886c-5ab1-43a6-8850-18b74dd54689'	System	26 Apr 2021 21:18:11
User entered 'No (N)'	System	26 Apr 2021 21:18:11

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Have you been exposed to someone with 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 (b5142763cae9e7cb)', Time: '2021-04-26T17:18:05-04:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'b7e8886c-5ab1-43a6-8850-18b74dd54689'	System	26 Apr 2021 21:18:11
User entered 'No (N)'	System	26 Apr 2021 21:18:11

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2021-04-26T17:18:08-04:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'b7e8886c-5ab1-43a6-8850-18b74dd54689'	System	26 Apr 2021 21:18:11
User entered '26 Apr 2021 17:18:08'	System	26 Apr 2021 21:18:11

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[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 (b5142763cae9e7cb)', Time: '2021-04-30T13:36:16-04:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '6f233ffe-f6ea-4cc0-902b-5ecec4f79f4'	System	30 Apr 2021 17:36:26
User entered 'No (N)'	System	30 Apr 2021 17:36:26

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Have you been exposed to someone with 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 (b5142763cae9e7cb)', Time: '2021-04-30T13:36:20-04:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '6f233ffe-f6ea-4cc0-902b-5ecec4f79f4'	System	30 Apr 2021 17:36:26
User entered 'No (N)'	System	30 Apr 2021 17:36:26

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2021-04-30T13:36:23-04:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: '6f233ffe-f6ea-4cc0-902b-5ecec4f79f4'	System	30 Apr 2021 17:36:26
User entered '30 Apr 2021 13:36:23'	System	30 Apr 2021 17:36:26

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 02:38:24

US3602004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:24
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 02:38:24

US3602004

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:08:05

[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 15:11:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2021-03-01T18:23:54-05:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'bd6167c8-8b0d-48b0-83df-09bc5685fedf'	System	01 Mar 2021 23:24:00
User entered 'No (N)'	System	01 Mar 2021 23:24:00

US3602004

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:08:05

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:11:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5142763cae9e7cb)', Time: '2021-03-01T18:23:58-05:00', User OID: 'PatientReportedOutcome (US3602004)', ODM File OID: 'bd6167c8-8b0d-48b0-83df-09bc5685fedf' User entered '01 Mar 2021 18:23:58'	System	01 Mar 2021 23:24:00
	System	01 Mar 2021 23:24:00

US3602004

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:04:13

US3602004

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '25 Nov 2020'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:04:13

US3602004

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:04:13

US3602004

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:04:13

US3602004

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:03:52

US3602004

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:50
User entered 'I'	System	30 Nov 2020 17:03:52

US3602004

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:55:56

US3602004

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
Signature has been broken.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:05:29
User entered '29 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 17:05:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '30 Dec 2020'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:55:56

US3602004

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:55:56

US3602004

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:55:56

US3602004

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:55:39

US3602004

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User entered 'I'	System	26 Jan 2021 19:55:39

US3602004

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:39:28

US3602004

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	09 Feb 2021 08:09:32
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'Subject was unable to reach study personel to return call from 1/28/21' (Site from System).	(b) (4), (b) (6)	08 Feb 2021 19:39:31
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	08 Feb 2021 19:39:28
User entered '3 Feb 2021'	(b) (4), (b) (6)	08 Feb 2021 19:39:28

US3602004

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:39:28

US3602004

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Subject was unable to reach study personel to return call from 1/28/21'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:39:28

US3602004

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:39:37

US3602004

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User entered 'I'	System	08 Feb 2021 19:39:37

US3602004

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 02:32:33

US3602004

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 04:50:54
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Confirming that call was completed one day out of safety call window.' (Site from System).	(b) (4), (b) (6)	03 Mar 2021 20:01:53
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	03 Mar 2021 20:00:17
User entered '1 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 20:00:17
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	02 Mar 2021 02:50:06
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	02 Mar 2021 02:50:06
User entered '28 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 02:50:06
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	02 Mar 2021 02:32:33
User entered '1 Mar 2021'	(b) (4), (b) (6)	02 Mar 2021 02:32:33

PRODUCTION RELEASE (v12.003
EAB) (1725)

1722 of 2600

US3602004

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 02:32:33

US3602004

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 02:32:33

US3602004

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:02:04

US3602004

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User entered 'I'	System	03 Mar 2021 20:02:04

US3602004

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 13:27:41

US3602004

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 13:27:41

US3602004

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 13:27:41

US3602004

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User entered 'VISIT4'	System	29 Mar 2021 13:27:41

US3602004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 13:28:45

US3602004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 13:28:45

US3602004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered '08:39'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 13:28:45

US3602004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User entered '29 Mar 2021 08:39'	System	29 Mar 2021 13:28:45

US3602004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	29 Mar 2021 13:28:45

US3602004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 13:28:45

US3602004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered 'Temporal'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 13:28:45

US3602004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered '57'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 13:28:45

US3602004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User entered 'bpm'	System	29 Mar 2021 13:28:45

US3602004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered '18'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 13:28:45

US3602004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User entered 'breaths/min'	System	29 Mar 2021 13:28:45

US3602004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered '121'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 13:28:45

US3602004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User entered 'mmHg'	System	29 Mar 2021 13:28:45

US3602004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered '60'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 13:28:45

US3602004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User entered 'mmHg'	System	29 Mar 2021 13:28:45

US3602004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10

US3602004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10

US3602004

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:08:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 13:29:01

US3602004

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:08:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 13:29:01

US3602004

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 13:29:26

US3602004

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 13:29:26

US3602004

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered '08:50'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 13:29:26

US3602004

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User entered '29 Mar 2021 08:50'	System	29 Mar 2021 13:29:26

US3602004

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 13:29:31

US3602004

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:10
User entered 'I'	System	29 Mar 2021 13:29:31

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:08:05

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:05
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:42:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '06 Dec 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:23:49

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:08:05

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:05
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 23:43:07
User closed query 'Per progress note, time was 0815. Verify and update data.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 23:38:51
Query 'Per progress note, time was 0815. Verify and update data.' answered with 'Confirming that time of contact was 08:15 and data has been updated.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 21:51:12
Signature has been broken.	(b) (4), (b) (6)	04 Mar 2021 21:50:12
User entered '08:15' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 21:50:12
User opened query 'Per progress note, time was 0815. Verify and update data.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 17:43:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '08:13'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:23:49

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:08:05

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:05
User entered '06 Dec 2020 08:15'	System	04 Mar 2021 21:50:12
User entered '06 Dec 2020 08:13'	System	07 Dec 2020 17:23:49

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:08:05

Type of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:05
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 14:49:48
User closed query 'The type of contact is recorded as Safety Call, but the the subject called the 24-hour line. The data was not obtained via a Safety Call. Update type of contact to reflect subject called 24-hour line.' (Site from CRA).	(b) (4), (b) (6)	11 Mar 2021 14:49:45
Query 'The type of contact is recorded as Safety Call, but the the subject called the 24-hour line. The data was not obtained via a Safety Call. Update type of contact to reflect subject called 24-hour line.' answered with 'As per CCG v5 pg. 59, "Any time during the course of the study a participant initiates a call with the site at an unscheduled time choose "Safety Call." Subject called the hotline which connected them with a study staff member.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 14:17:50
User opened query 'The type of contact is recorded as Safety Call, but the the subject called the 24-hour line. The data was not obtained via a Safety Call. Update type of contact to reflect subject called 24-hour line.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 23:43:03
User closed query 'Per progress note, subject called 24-hour line at 0815 on 12/6/20 to report symptoms. Please verify and update this data.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 23:43:03
Query 'Per progress note, subject called 24-hour line at 0815 on 12/6/20 to report symptoms. Please verify and update this data.' answered with 'Confirming that subject called 24-hour line at 08:15h on 06-Dec-2020.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 21:54:18
User opened query 'Per progress note, subject called 24-hour line at 0815 on 12/6/20 to report symptoms. Please verify and update this data.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 17:42:49
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Safety Call (Safety Call)'	(b) (4), (b) (6)	07 Dec 2020 17:23:49

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:08:05

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:05
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:43:36
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:23:49

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:08:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:03

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:08:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:45:38
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '04 Dec 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:03

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:08:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:45:38
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:03

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:45:38
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:03

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User entered '%'	System	07 Dec 2020 17:27:03

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:08:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:45:38
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:03

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:08:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:45:38
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:03

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:08:05

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:46:50
User closed query 'On Illness visit day 2 on 12/8/20, progress note indicated the subject continues to experience cough. This was not a symptom what was reported on 12/7/20 during the illness visit. Confirm date cough started.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 23:46:48
Query 'On Illness visit day 2 on 12/8/20, progress note indicated the subject continues to experience cough. This was not a symptom what was reported on 12/7/20 during the illness visit. Confirm date cough started.' answered with 'Confirming symptom "cough" start date was 04-Dec-2020 as per symptom grid in section "ROS Specific to COVID-19" in Illness Visit progress notes on 07-Dec-2020.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 22:36:39
User opened query 'On Illness visit day 2 on 12/8/20, progress note indicated the subject continues to experience cough. This was not a symptom what was reported on 12/7/20 during the illness visit. Confirm date cough started.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 17:57:37
Query 'Progress note did not indicate cough was reported. Verify and update data.' canceled (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 17:53:19
User opened query 'Progress note did not indicate cough was reported. Verify and update data.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 17:47:01
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:45:49
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:45:38
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Mild (Mild)'	(b) (4), (b) (6)	07 Dec 2020 17:27:03

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:08:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:45:38
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:03

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:08:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:45:38
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:03

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:08:05

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:46:58
User closed query 'On Illness visit day 2 on 12/8/20, progress note indicated the subject continues to experience fatigue. This was not a symptom what was reported on 12/7/20 during the illness visit. Confirm date fatigue started.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 23:46:55
Query 'On Illness visit day 2 on 12/8/20, progress note indicated the subject continues to experience fatigue. This was not a symptom what was reported on 12/7/20 during the illness visit. Confirm date fatigue started.' answered with 'Confirming symptom "fatigue" start date was 04-Dec-2020 as per symptom grid in section "ROS Specific to COVID-19" in Illness Visit progress notes on 07-Dec-2020.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 22:36:43
User opened query 'On Illness visit day 2 on 12/8/20, progress note indicated the subject continues to experience fatigue. This was not a symptom what was reported on 12/7/20 during the illness visit. Confirm date fatigue started.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 17:56:46
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:47:07
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:45:38
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Mild (Mild)'	(b) (4), (b) (6)	07 Dec 2020 17:27:03

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:08:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:45:38
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:03

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:08:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:45:38
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:03

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:08:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:45:38
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Moderate (Moderate)' reason for change: New Information	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 18:28:36
User entered 'None (None)'	(b) (4), (b) (6)	07 Dec 2020 17:27:03

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:45:38
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:03

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:45:38
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:03

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:08:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:45:38
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:03

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:08:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:45:38
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:03

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:08:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:45:38
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:03

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:08:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:45:38
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:03

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:08:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:45:38
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:03

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:08:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:45:38
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:03

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:08:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:52

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:08:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:01:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '05 Dec 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:52

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:08:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:01:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:52

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:01:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:52

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User entered '%'	System	07 Dec 2020 17:27:52

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:08:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:01:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:52

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:08:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:01:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:52

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:08:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
Query 'See query posted for cough on 12/4/20.' canceled (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 18:03:35
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 18:01:49
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:01:43
User opened query 'See query posted for cough on 12/4/20.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 18:01:13
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:52

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:08:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:01:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:52

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:08:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:01:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:52

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:08:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
Query 'See query posted for fatigue on 12/4/20.' canceled (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 18:03:38
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 18:01:52
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:01:43
User opened query 'See query posted for fatigue on 12/4/20.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 18:01:32
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:52

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:08:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:01:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:52

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:08:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:01:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:52

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:08:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:01:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Moderate (Moderate)' reason for change: New Information	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 18:28:36
User entered 'None (None)'	(b) (4), (b) (6)	07 Dec 2020 17:27:52

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:01:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:52

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:01:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:52

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:08:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:01:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:52

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:08:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:01:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:52

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:08:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:01:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:52

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:08:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:01:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:52

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:08:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:01:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:52

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:08:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:01:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:27:52

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:08:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:32:39

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:08:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:02:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '06 Dec 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:32:39

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:08:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:02:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:32:39

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:02:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:32:39

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User entered '%'	System	07 Dec 2020 17:32:39

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:08:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:02:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:32:39

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:08:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:02:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:32:39

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:08:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:00:14
Query 'See query posted for cough on 12/4/20.' canceled (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 18:03:15
User opened query 'See query posted for cough on 12/4/20.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 18:02:59
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 18:02:45
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:02:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Mild (Mild)'	(b) (4), (b) (6)	07 Dec 2020 17:32:39

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:08:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:02:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:32:39

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:08:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:02:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:32:39

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:08:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 18:03:03
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:02:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:32:39

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:08:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:02:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:32:39

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:08:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:02:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:32:39

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:08:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:02:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Moderate (Moderate)' reason for change: New Information	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 18:28:36
User entered 'None (None)'	(b) (4), (b) (6)	07 Dec 2020 17:32:39

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:02:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:32:39

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:02:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:32:39

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:08:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:02:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:32:39

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:08:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:02:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:32:39

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:08:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:02:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:32:39

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:08:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:02:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:32:39

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:08:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:02:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:32:39

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:08:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:02:27
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:32:39

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:08:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:33:43

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:08:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:07:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '07 Dec 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:33:43

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:08:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:07:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:33:43

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:07:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '98'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:33:43

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User entered '%'	System	07 Dec 2020 17:33:43

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:08:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:07:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '97.4' F	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:33:43

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:08:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:07:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:33:43

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:08:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:00:22
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 18:07:39
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:07:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:33:43

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:08:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:07:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:33:43

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:08:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:07:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:33:43

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:08:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:00:26
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 18:07:48
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:07:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:33:43

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:08:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:07:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:33:43

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:08:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:07:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:33:43

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:08:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:07:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Moderate (Moderate)' reason for change: New Information	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 18:28:36
User entered 'None (None)'	(b) (4), (b) (6)	07 Dec 2020 17:33:43

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:07:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:33:43

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:07:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:33:43

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:08:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:07:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:33:43

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:08:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:07:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:33:43

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:08:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:07:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:33:43

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:08:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:07:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:33:43

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:08:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:07:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:33:43

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:08:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:07:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:33:43

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:08:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:12:48

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:08:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:13:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '08 Dec 2020'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:12:48

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:08:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:13:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:12:48

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:13:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '91'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:12:48

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User entered '%'	System	09 Dec 2020 17:12:48

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:08:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:13:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '99.2' F	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:12:48

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:08:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:13:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:12:48

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:08:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:13:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:12:48

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:08:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:13:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:12:48

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:08:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:13:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:12:48

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:08:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:13:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:12:48

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:08:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:13:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:12:48

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:08:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:13:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:12:48

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:08:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:13:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:12:48

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:13:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:12:48

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:13:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:12:48

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:08:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:13:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:12:48

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:08:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:13:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:12:48

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:08:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:13:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:12:48

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:08:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:13:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:12:48

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:08:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:13:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:12:48

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:08:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:13:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:12:48

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:08:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:30:58

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:08:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:01:01
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '09 Dec 2020'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:30:58

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:08:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:01:03
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:30:58

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:01:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '96'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:30:58

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User entered '%'	System	15 Dec 2020 15:30:58

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:08:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:30:58

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:08:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:01:28
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:30:58

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:08:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:01:35
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:30:58

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:08:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:01:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:30:58

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:08:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:02:16
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:30:58

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:08:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:02:19
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:30:58

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:08:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:02:26
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:30:58

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:08:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:02:35
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:30:58

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:08:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:02:53
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:30:58

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:03:02
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:30:58

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:03:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:30:58

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:08:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:03:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:30:58

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:08:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:03:18
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:30:58

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:08:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:03:24
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:30:58

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:08:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:03:28
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:30:58

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:08:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:03:42
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:30:58

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:08:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:03:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:30:58

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:08:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:31:53

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:08:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:07:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '10 Dec 2020'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:31:53

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:08:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:07:16
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:31:53

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:07:18
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '97'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:31:53

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User entered '%'	System	15 Dec 2020 15:31:53

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:08:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:07:24
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '98.4' F	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:31:53

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:08:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:07:26
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:31:53

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:08:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:07:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:31:53

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:08:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:07:56
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:31:53

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:08:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:07:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:31:53

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:08:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:07:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:31:53

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:08:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:08:02
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:31:53

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:08:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:08:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:31:53

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:08:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:08:06
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:31:53

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:08:07
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:31:53

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:08:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:31:53

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:08:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:08:26
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:31:53

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:08:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:08:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:31:53

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:08:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:08:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:31:53

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:08:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:08:34
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:31:53

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:08:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:08:37
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:31:53

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:08:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:08:39
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:31:53

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:08:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:32:40

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:08:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:32:40

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:08:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:32:40

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:32:40

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User entered '%'	System	15 Dec 2020 15:32:40

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:08:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:32:40

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:08:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:32:40

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:08:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:32:40

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:08:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:32:40

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:08:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:32:40

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:08:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:32:40

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:08:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:32:40

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:08:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:32:40

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:08:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:32:40

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:32:40

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:32:40

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:08:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:32:40

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:08:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:32:40

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:08:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:32:40

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:08:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:32:40

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:08:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:32:40

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:08:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:32:40

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:08:05

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:22
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:32:33
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '7 Dec 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:34:05

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:08:05

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:22
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:32:33
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:34:05

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:08:05

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:22
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:32:33
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User closed query 'Per CDM : Please keep Query open until resolution. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 03:45:34
Query 'Per CDM : Please keep Query open until resolution. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 15:36:18
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	11 Dec 2020 15:36:06
User opened query 'Per CDM : Please keep Query open until resolution. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 11:58:30
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	08 Dec 2020 11:58:11
Query 'Data is required. Please complete.' answered with 'will update once results are received' (Site from System).	(b) (4), (b) (6)	07 Dec 2020 17:34:18
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 17:34:05
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 17:34:05

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:08:05

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:22
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:32:33
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '7 Dec 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:34:05

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:08:05

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:22
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:32:33
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	07 Dec 2020 17:34:05

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:08:05

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:22
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:32:33
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:34:05

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:08:05

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:22
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:32:33
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:34:05

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:08:05

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:22
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:32:33
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:34:05

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:08:05

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:22
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:32:33
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:34:05

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:08:05

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:22
User entered '0'	System	11 Dec 2020 15:36:06

US3602004

Folder: Covid-19 Assessment 06 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:08:05

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:50:30
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:32:46
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:36:06

US3602004

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:08:05

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:38
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	09 Dec 2020 18:58:28

US3602004

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:08:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:38
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:10:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:58:28

US3602004

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:08:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:38
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:10:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '9 Dec 2020'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:58:28

US3602004

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:08:05

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:38
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	15 Dec 2020 15:29:38

US3602004

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:08:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:38
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:10:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:29:38

US3602004

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:08:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:38
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:10:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:29:38

US3602004

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:08:05

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:38
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	15 Dec 2020 15:29:38

US3602004

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:08:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:38
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:10:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:29:38

US3602004

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:08:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:38
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:10:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:29:38

US3602004

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:08:05

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:38
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	15 Dec 2020 15:29:38

US3602004

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:08:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:38
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:10:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:29:38

US3602004

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:08:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:38
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:10:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:29:38

US3602004

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:08:05

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:38
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	15 Dec 2020 15:29:38

US3602004

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:08:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:38
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:10:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:29:38

US3602004

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:08:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:38
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:10:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:29:38

US3602004

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:08:05

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:38
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	15 Dec 2020 15:29:38

US3602004

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:08:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:38
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:10:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:29:38

US3602004

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:08:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:38
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:10:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:29:38

US3602004

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:08:05

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:38
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	15 Dec 2020 15:29:38

US3602004

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:08:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:38
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:10:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:29:38

US3602004

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:08:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:38
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:10:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:29:38

US3602004

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:21:50
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:32:06
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:34:30

US3602004

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:21:50
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:32:06
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 12:09:13
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 15:29:44
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 10:59:32
User entered '7 Dec 2020'	(b) (4), (b) (6)	07 Dec 2020 17:34:30

US3602004

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:21:50
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:32:06
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:34:30

US3602004

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:21:50
User entered 'SICKD1'	System	07 Dec 2020 17:34:30

US3602004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:34:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:35:38

US3602004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:34:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '7 Dec 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:35:38

US3602004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:12
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:50:31
User closed query 'Progress note indicated VS conducted at 0933. Verify and update data.' (Site from CRA).	(b) (4), (b) (6)	11 Mar 2021 14:50:26
Query 'Progress note indicated VS conducted at 0933. Verify and update data.' answered with 'Data has been updated as per progress notes.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 21:46:09
Signature has been broken.	(b) (4), (b) (6)	04 Mar 2021 21:45:47
User entered '09:33' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 21:45:47
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:34:21
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:34:17
User opened query 'Progress note indicated VS conducted at 0933. Verify and update data.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 17:33:49
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '09:30'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:35:38

US3602004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:12
User entered '7 Dec 2020 09:33'	System	04 Mar 2021 21:45:47
User entered '7 Dec 2020 09:30'	System	07 Dec 2020 17:35:38

US3602004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:34:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:35:38
DataPoint set to visible.	System	07 Dec 2020 17:34:30

US3602004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:34:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:35:38
DataPoint set to visible.	System	07 Dec 2020 17:34:30

US3602004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:34:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '97.4' F	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:35:38

US3602004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:34:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:35:38

US3602004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:34:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'TEMPORAL'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:35:38

US3602004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:34:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '70'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:35:38

US3602004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:12
User entered 'bpm'	System	07 Dec 2020 17:35:38

US3602004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:34:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '18'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:35:38

US3602004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:12
User entered 'breaths/min'	System	07 Dec 2020 17:35:38

US3602004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:34:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User closed query 'Per CDM: Please confirm if Systolic BP is CS or NCS, as there is no Hypertension reported in Medical History. Please review and update CRF as necessary. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 06:28:22
Query 'Per CDM: Please confirm if Systolic BP is CS or NCS, as there is no Hypertension reported in Medical History. Please review and update CRF as necessary. Thank you' answered with 'NCS per provider' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 18:58:59
User opened query 'Per CDM: Please confirm if Systolic BP is CS or NCS, as there is no Hypertension reported in Medical History. Please review and update CRF as necessary. Thank you' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 18:08:33
User entered '160'	(b) (4), (b) (6)	07 Dec 2020 17:35:38

US3602004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:12
User entered 'mmHg'	System	07 Dec 2020 17:35:38

US3602004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:12
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:34:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '81'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:35:38

US3602004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:12
User entered 'mmHg'	System	07 Dec 2020 17:35:38

US3602004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:12

US3602004

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:12

US3602004

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:08:05

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:20
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 02:44:39
User closed query 'Progress note indicated subject was seen in the Illness Tent. Vitals, blood draw, NP swab, and teaching on collecting saliva samples were completed. CRA was unable to find a progress note about PE being completed. Please clarify where this information was recorded.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 02:44:36
Query 'Progress note indicated subject was seen in the Illness Tent. Vitals, blood draw, NP swab, and teaching on collecting saliva samples were completed. CRA was unable to find a progress note about PE being completed. Please clarify where this information was recorded.' answered with 'PE information was recorded beneath Illness Visit Vital Signs in Illness Visit progress notes on 07-Dec-2020.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 22:39:23
User opened query 'Progress note indicated subject was seen in the Illness Tent. Vitals, blood draw, NP swab, and teaching on collecting saliva samples were completed. CRA was unable to find a progress note about PE being completed. Please clarify where this information was recorded.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 17:39:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Dec 2020 17:35:52

US3602004

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:08:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:20
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 02:44:39
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '7 Dec 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:35:52

US3602004

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:08:05

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:29
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:39:56
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:36:00

US3602004

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:08:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:22:29
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:39:56
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '7 Dec 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:36:00

US3602004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 15:37:43

US3602004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '08 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 15:37:43

US3602004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 15:37:43

US3602004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered 'UNBLND_DECIDE'	System	11 Jan 2021 15:37:43

US3602004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:08:05

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '08 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 15:38:00

US3602004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:08:05

[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 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 00:12:33
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:00:52

US3602004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:08:05

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 15:38:00

US3602004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:08:05

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 00:12:33
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:00:52

US3602004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:08:05

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '08 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 15:38:00

US3602004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:08:05

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 15:38:00

US3602004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:08:05

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 08:56:07
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	11 Jan 2021 15:38:00

US3602004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:08:05

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 08:56:07
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	11 Jan 2021 15:38:00

US3602004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:08:05

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 15:38:00

US3602004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:08:05

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered empty.	System	11 Jan 2021 15:38:00

US3602004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:08:05

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered empty.	System	11 Jan 2021 15:38:00

US3602004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 15:38:19

US3602004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '08 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 15:38:19

US3602004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '11:32'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 15:38:19

US3602004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered '08 Jan 2021 11:32'	System	11 Jan 2021 15:38:19

US3602004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:08:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 15:37:31

US3602004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:08:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '08 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 15:37:31

US3602004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:08:05

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '11:30'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 15:37:31

US3602004

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:08:05

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:35
User entered '08 Jan 2021 11:30'	System	11 Jan 2021 15:37:31

US3602004

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:08:05

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:46:05
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:21:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	09 Oct 2020 18:22:03
User closed query 'Per CDM: Re-query: Response confirms participant did not experience an AE. Please select form the drop down list the corresponding option. Thanks' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 03:48:19
Query 'Per CDM: Re-query: Response confirms participant did not experience an AE. Please select form the drop down list the corresponding option. Thanks' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 13:26:33
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	18 Sep 2020 13:25:15
User opened query 'Per CDM: Re-query: Response confirms participant did not experience an AE. Please select form the drop down list the corresponding option. Thanks' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 09:17:53
User closed query 'Per CDM: Response noted, Kindly update the response for ' Did the participant experience any AE?' as Yes or No . thank you' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 09:17:53
Query 'Per CDM: Response noted, Kindly update the response for ' Did the participant experience any AE?' as Yes or No . thank you' answered with 'The participant did not experience an AE.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 12:53:18
User opened query 'Per CDM: Response noted, Kindly update the response for ' Did the participant experience any AE?' as Yes or No . thank you' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 05:14:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 05:13:28
Query 'Data is required. Please complete.' answered with 'Data not required. no AE reported. ' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 14:48:48
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 20:18:21

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EAB) (1725)

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US3602004

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:08:05

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 20:18:21
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 18:47:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Sep 2020 18:47:28
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 18:47:28
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 18:47:21
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 18:47:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 18:42:51

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[AEID](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 04:52:55
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' answered with 'yes, illness visit was on 12/7/2020' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 16:21:56
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 05:02:31
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Paranasal sinus disorders (excl infections and neoplasms), PT: Sinus congestion, LLT: Sinus congestion - version MedDRA\23.0.	Coder Import (b) (4)	15 Dec 2020 17:13:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	15 Dec 2020 17:13:58
Data point term sent to Coder	System	15 Dec 2020 16:11:12
Coding entries removed.	(b) (4), (b) (6)	15 Dec 2020 16:10:38
User entered 'Right Sinus Congestion' reason for change: New Information	(b) (4), (b) (6)	15 Dec 2020 16:10:38
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Paranasal sinus disorders (excl infections and neoplasms), PT: Sinus congestion, LLT: Sinus congestion - version MedDRA\23.0.	Coder Import (b) (4)	07 Dec 2020 19:21:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	07 Dec 2020 19:21:58
Data point term sent to Coder	System	07 Dec 2020 17:41:22
User entered 'CONGESTION (R FRONTAL SINUSES SUPRA AND SUB OCULAR)'	(b) (4), (b) (6)	07 Dec 2020 17:40:25

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Dec 2020 17:40:25

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4), (b) (6)	07 Dec 2020 17:40:25

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4), (b) (6)	07 Dec 2020 17:40:25

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '04 Dec 2020'	(b) (4), (b) (6)	07 Dec 2020 17:40:25

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 17:40:25

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07
User entered empty.	System	07 Dec 2020 17:40:25

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	15 Dec 2020 15:33:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Dec 2020 17:40:25

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:31
Signature has been broken.	(b) (4), (b) (6)	26 Feb 2021 21:02:24
User entered '11 Dec 2020' reason for change: New Information	(b) (4), (b) (6)	26 Feb 2021 21:02:24
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '09 Dec 2020' reason for change: New Information	(b) (4), (b) (6)	15 Dec 2020 15:33:40
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 17:40:25

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 17:40:25

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07
User entered empty.	System	07 Dec 2020 17:40:25

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Severity](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	07 Dec 2020 17:40:25

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4), (b) (6)	07 Dec 2020 17:40:25

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Death](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '0'	(b) (4), (b) (6)	07 Dec 2020 17:40:25

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Life threatening](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '0'	(b) (4), (b) (6)	07 Dec 2020 17:40:25

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '0'	(b) (4), (b) (6)	07 Dec 2020 17:40:25

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 17:40:25

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 17:40:25

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 17:40:25

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 17:40:25

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '0'	(b) (4), (b) (6)	07 Dec 2020 17:40:25

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '0'	(b) (4), (b) (6)	07 Dec 2020 17:40:25

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '0'	(b) (4), (b) (6)	07 Dec 2020 17:40:25

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	07 Dec 2020 17:40:25

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	07 Dec 2020 17:40:25

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:40:25

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[None](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '0'	(b) (4), (b) (6)	07 Dec 2020 17:40:25

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'I'	(b) (4), (b) (6)	07 Dec 2020 17:40:25

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '0'	(b) (4), (b) (6)	07 Dec 2020 17:40:25

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Outcome](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:33:40
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	07 Dec 2020 17:40:25

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 17:40:25

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Narrative](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 17:40:25

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07
User entered '0'	System	07 Dec 2020 17:40:25

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07
User entered 'I'	System	07 Dec 2020 17:40:25

US3602004

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 16:55:09
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:07

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:18:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 04:53:01
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' answered with 'yes, illness visit was on 12/7/2020' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 16:22:06
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 05:02:42
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest discomfort, LLT: Chest tightness - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 19:01:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 19:01:50
Data point term sent to Coder	System	09 Dec 2020 17:17:23
User entered 'Intermittent Chest Tightness'	(b) (4), (b) (6)	09 Dec 2020 17:16:24

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:18:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:16:24

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:18:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:16:24

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:18:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:16:24

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:18:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '8 Dec 2020'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:16:24

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:18:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:16:24

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16
User entered empty.	System	09 Dec 2020 17:16:24

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:18:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	17 Dec 2020 15:38:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Dec 2020 17:16:24

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:18:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '08 Dec 2020' reason for change: New Information	(b) (4), (b) (6)	17 Dec 2020 15:38:52
User entered empty.	(b) (4), (b) (6)	09 Dec 2020 17:16:24

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:18:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:16:24

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16
User entered empty.	System	09 Dec 2020 17:16:24

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:18:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:16:24

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:18:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:16:24

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:18:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:16:24

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:18:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:16:24

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:18:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:16:24

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:18:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:16:24

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:18:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:16:24

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:18:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:16:24

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:18:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:16:24

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:18:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:16:24

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:18:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:16:24

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:18:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '0'	(b) (4), (b) (6)	09 Dec 2020 17:16:24

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:18:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:16:24

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:18:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:16:24

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:18:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:16:24

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:18:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'l'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:16:24

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:18:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '0'	(b) (4), (b) (6)	09 Dec 2020 17:16:24

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:18:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:16:24

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:18:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:38:52
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	09 Dec 2020 17:16:24

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:18:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:16:24

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:18:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 17:16:24

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16
User entered '0'	System	09 Dec 2020 17:16:24

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16
User entered '0'	System	09 Dec 2020 17:16:24

US3602004

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:08:05

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:12:16

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 00:18:05
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:17:55
User entered		
'USA-US079-2021-mRNA-1273-P301000003'	System	26 Feb 2021 16:19:36
User entered 'New'	(b) (4), (b) (6)	26 Feb 2021 16:19:36

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:18:05
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Acute myocardial infarction, LLT: Non ST segment elevation myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 23:46:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 23:46:05
Data point term sent to Coder	System	25 Feb 2021 21:10:29
User entered 'NSTEMI (Non-ST Segment Elevation Myocardial Infarction)'	(b) (4), (b) (6)	25 Feb 2021 21:09:54

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:18:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Feb 2021 21:09:54

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:18:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 21:09:54

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:18:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 21:09:54

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:18:05
User entered '3 Jan 2021'	(b) (4), (b) (6)	25 Feb 2021 21:09:54

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:18:05
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 21:09:54

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 21:09:54

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:18:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 21:09:54

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:18:05
User entered '4 Jan 2021'	(b) (4), (b) (6)	25 Feb 2021 21:09:54

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:18:05
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 21:09:54

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 21:09:54

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:18:05
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	25 Feb 2021 21:09:54

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:18:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Feb 2021 21:09:54

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 00:18:05
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 21:09:54

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 00:18:05
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 21:09:54

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:18:05
User entered 'I'	(b) (4), (b) (6)	25 Feb 2021 21:09:54

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:18:05
User entered '3 Jan 2021'	(b) (4), (b) (6)	25 Feb 2021 21:09:54

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 00:18:05
User closed query 'PV Query: Per the narrative, the subject was discharged from the hospital on 04 Jan 2021. Please update the eCRF to reflect this.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 15:12:30
Query 'PV Query: Per the narrative, the subject was discharged from the hospital on 04 Jan 2021. Please update the eCRF to reflect this.' answered with 'Discharge date has been corrected as per progress notes' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 19:25:30
User entered '4 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 19:24:45
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 18:10:36
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 17:26:29
User opened query 'PV Query: Per the narrative, the subject was discharged from the hospital on 04 Jan 2021. Please update the eCRF to reflect this.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 17:26:10
User entered '4 Feb 2021'	(b) (4), (b) (6)	25 Feb 2021 21:09:54

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:18:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 21:09:54

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:18:05
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 21:09:54

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 00:18:05
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 21:09:54

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 00:18:05
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 21:09:54

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 00:18:05
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 21:09:54

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:18:05
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	25 Feb 2021 21:09:54

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:18:05
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	25 Feb 2021 21:09:54

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:18:05
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	25 Feb 2021 21:09:54

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 00:18:05
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 21:09:54

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 00:18:05
User entered 'I'	(b) (4), (b) (6)	25 Feb 2021 21:09:54

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 00:18:05
User entered 'I'	(b) (4), (b) (6)	25 Feb 2021 21:09:54

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:18:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	25 Feb 2021 21:09:54

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:18:05
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 21:09:54

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per CDM Re-Query: Please note that diagnostic can be entered, it is an available option on the Procedure's indication, as well as Adverse Event. Please review CRF and update accordingly (CRF Guidelines page 54-55). Thank you' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 04:09:46
Query 'Per CDM Re-Query: Please note that diagnostic can be entered, it is an available option on the Procedure's indication, as well as Adverse Event. Please review CRF and update accordingly (CRF Guidelines page 54-55). Thank you' answered with 'Blood Work-up has been recorded in ConProc log. (Previously cited "Diagnostic" drop down menu option and CCG pg. 54-55 as reasons for adding Diagnostic Procedures to ConProc Log, but was still instructed not to record these in the ConProc Log.)' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 16:07:11
User opened query 'Per CDM Re-Query: Please note that diagnostic can be entered, it is an available option on the Procedure's indication, as well as Adverse Event. Please review CRF and update accordingly (CRF Guidelines page 54-55). Thank you' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 15:22:06
User closed query 'Per DM CLR: Narrative = TROPONIN. However, this is not recorded in the ConProc eCRF (i.e., Blood work-up). Please review and ensure that this is captured in the appropriate eCRF. (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 15:22:06
Query 'Per DM CLR: Narrative = TROPONIN. However, this is not recorded in the ConProc eCRF (i.e., Blood work-up). Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'As per previous queries, Diagnostic Procedures should not be recorded in the ConProc Log, only treatment procedures should be recorded.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 04:03:56
User opened query 'Per DM CLR: Narrative = TROPONIN. However, this is not recorded in the ConProc eCRF (i.e., Blood work-up). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 23:23:14

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:18:05
User entered 'ON 3/JAN 2021 AT 2300 UPON STANDING UP SHE REPORTS THAT SHE BEGAN TO EXPERIENCE CHEST PRESSURE, WHICH SHE DESCRIBED AS " A HEAVINESS, LIKE SOMEONE WAS SITTING ON MY CHEST". SHE CALLED 911. SHE WAS TRANSPORTED TO LOCAL ER VIA AMBULANCE. SHE WAS GIVEN ASPIRIN, NITROGLYCERIN, AND LOPRESSOR, IN THE ER. SHE REPORTS THAT CHEST PRESSURE AND SHORTNESS BEGAN TO RESOLVE UPON TAKING NITROGLYCERIN. SHE REPORTS THAT ALL THE CHEST DISCOMFORT AND SHORTNESS OF BREATH COMPLETELY RESOLVED BY 0300 ON 4/JAN/2021.THE EKG REVEALED A NSTEMI. HER TROPONIN'S WERE GROSSLY POSITIVE. UPON THE RETURN OF POSITIVE TROPONIN SHE WAS TRANSPORTED TO CATH LAB WHERE CARDIAC CATHETERIZATION WAS PERFORMED. SHE DID NOT REQUIRE STENTS- SHE REPORTS THAT THE CARDIAC CATHETERIZATION REVELED MINOR PLAQUES BUT "NO BLOCKAGE". SHE IS SCHEDULE FOR FOLLOW UP APPOINTMENT WITH CARDIOLOGIST 12/JAN/2021. UPON DISCHARGE FROM THE HOSPITAL AT 1500 ON 4/JAN/2021 SHE WAS PRESCRIBED 81MG OF ASPIRIN DAILY. AT THE TIME OF TELEPHONE CONTACT SHE REPORTS THAT SHE IS ASYMPTOMATIC. PI MADE AWARE OF MAAE. COVID-19 TESTING WAS NOT PERFORMED AT HOSPITAL. TROPONIN LEVELS WERE AS FOLLOWS: ON JAN 04 07:42: TROPONIN-L 0.17NG/ML HIGH; ON JAN 04 09:42: TROPONIN-L 0.16NG/ML HIGH. The normal troponin reference range is 0.00 to 0.04 ng/ml.' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 21:44:04

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results of the troponins that were grossly positive.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 15:17:47
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)	04 Mar 2021 15:17:44
Query 'PV Query: Please provide the results of the troponins that were grossly positive.' answered with 'Grossly positive troponin results have been added to SAE narrative.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 14:15:23
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'No COVID-19 testing was performed at hospital. This has been added to narrative.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 14:09:52

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Narrative](#)

Audit	User	Time (GMT)
User entered 'ON 3/JAN 2021 AT 2300 UPON STANDING UP SHE REPORTS THAT SHE BEGAN TO EXPERIENCE CHEST PRESSURE, WHICH SHE DESCRIBED AS " A HEAVINESS, LIKE SOMEONE WAS SITTING ON MY CHEST". SHE CALLED 911. SHE WAS TRANSPORTED TO LOCAL ER VIA AMBULANCE. SHE WAS GIVEN ASPIRIN, NITROGLYCERIN, AND LOPRESSOR, IN THE ER. SHE REPORTS THAT CHEST PRESSURE AND SHORTNESS BEGAN TO RESOLVE UPON TAKING NITROGLYCERIN. SHE REPORTS THAT ALL THE CHEST DISCOMFORT AND SHORTNESS OF BREATH COMPLETELY RESOLVED BY 0300 ON 4/JAN/2021.THE EKG REVEALED A NSTEMI. HER TROPONIN'S WERE GROSSLY POSITIVE. UPON THE RETURN OF POSITIVE TROPONIN SHE WAS TRANSPORTED TO CATH LAB WHERE Cardiac catheterization WAS PERFORMED. SHE DID NOT REQUIRE STENTS- SHE REPORTS THAT THE CARDIAC CATHETERIZATION REVELED MINOR PLAQUES BUT "NO BLOCKAGE". SHE IS SCHEDULE FOR FOLLOW UP APPOINTMENT WITH CARDIOLOGIST 12/JAN/2021. UPON DISCHARGE FROM THE HOSPITAL AT 1500 ON 4/JAN/2021 SHE WAS PRESCRIBED 81MG OF ASPIRIN DAILY. AT THE TIME OF TELEPHONE CONTACT SHE REPORTS THAT SHE IS ASYMPTOMATIC. PI MADE AWARE OF MAAE. COVID-19 testing was not performed at hospital. Troponin levels were as follows: On Jan 04 07:42: Troponin-I 0.17ng/ml High; On Jan 04 09:42: Troponin-I 0.16ng/ml High.'	(b) (4), (b) (6)	04 Mar 2021 14:08:45
reason for change: Data Entry Error		

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Narrative](#)

Audit	User	Time (GMT)
User entered 'ON 3/JAN 2021 AT 2300 UPON STANDING UP SHE REPORTS THAT SHE BEGAN TO EXPERIENCE CHEST PRESSURE, WHICH SHE DESCRIBED AS " A HEAVINESS, LIKE SOMEONE WAS SITTING ON MY CHEST". SHE CALLED 911. SHE WAS TRANSPORTED TO LOCAL ER VIA AMBULANCE. SHE WAS GIVEN ASPIRIN, NITROGLYCERIN, AND LOPRESSOR, IN THE ER. SHE REPORTS THAT CHEST PRESSURE AND SHORTNESS BEGAN TO RESOLVE UPON TAKING NITROGLYCERIN. SHE REPORTS THAT ALL THE CHEST DISCOMFORT AND SHORTNESS OF BREATH COMPLETELY RESOLVED BY 0300 ON 4/JAN/2021.THE EKG REVEALED A NSTEMI. HER TROPONIN'S WERE GROSSLY POSITIVE. UPON THE RETURN OF POSITIVE TROPONIN SHE WAS TRANSPORTED TO CATH LAB WHERE ANGIOPLASTY WAS PERFORMED. SHE DID NOT REQUIRE STENTS-SHE REPORTS THAT THE Cardiac Catheterization REVELED MINOR PLAQUES BUT "NO BLOCKAGE". SHE IS SCHEDULE FOR FOLLOW UP APPOINTMENT WITH CARDIOLOGIST 12/JAN/2021. UPON DISCHARGE FROM THE HOSPITAL AT 1500 ON 4/JAN/2021 SHE WAS PRESCRIBED 81MG OF ASPIRIN DAILY. AT THE TIME OF TELEPHONE CONTACT SHE REPORTS THAT SHE IS ASYMPTOMATIC. PI MADE AWARE OF MAAE.' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 19:24:45
User opened query 'PV Query: Please provide the results of the troponins that were grossly positive.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 17:27:04
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)	03 Mar 2021 17:26:53

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Narrative](#)

Audit	User	Time (GMT)
User entered 'on 3/Jan 2021 at 2300 upon standing up she reports that she began to experience chest pressure, which she described as " a heaviness, like someone was sitting on my chest". She called 911. She was transported to local ER via ambulance. She was given Aspirin, Nitroglycerin, and lopressor, in the ER. She reports that chest pressure and shortness began to resolve upon taking nitroglycerin. She reports that all the chest discomfort and shortness of breath completely resolved by 0300 on 4/Jan/2021.The EKG revealed a NSTEMI. Her troponin's were grossly positive. Upon the return of positive troponin she was transported to CATH lab where angioplasty was performed. She did not require stents- she reports that the angioplasty reveled minor plaques but "no blockage". She is schedule for follow up appointment with cardiologist 12/JAN/2021. Upon discharge from the hospital at 1500 on 4/Jan/2021 she was prescribed 81mg of Aspirin daily. At the time of telephone contact she reports that she is asymptomatic. PI made aware of MAAE.'	(b) (4), (b) (6)	25 Feb 2021 21:09:54

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 21:09:54

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Feb 2021 21:09:54

US3602004

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Feb 2021 21:09:54

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 06:14:56
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'Yes, subject was assessed for COVID-19 infection on 07-Dec-2020 during an Illness Visit.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 13:08:52
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 06:46:56
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory tract infection - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	08 Mar 2021 17:07:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Mar 2021 17:07:46
Data point term sent to Coder	System	08 Mar 2021 17:06:05
User entered 'Upper Respiratory Tract Infection'	(b) (4), (b) (6)	08 Mar 2021 17:06:02

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:06:02

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:06:02

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:06:02

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered '4 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:06:02

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:06:02

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58
User entered empty.	System	08 Mar 2021 17:06:02

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:06:02

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered '10 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:06:02

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:06:02

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58
User entered empty.	System	08 Mar 2021 17:06:02

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:06:02

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:06:02

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:06:02

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:06:02

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:06:02

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:06:02

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:06:02

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:06:02

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:06:02

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:06:02

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:06:02

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:06:02

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:06:02

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:06:02

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:06:02

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:06:02

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 09:22:42
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'ConMeds' indication has been updated for ConMeds taken for this AE.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 16:50:51
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 10:38:25
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered 'I'	(b) (4), (b) (6)	08 Mar 2021 17:06:02

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:06:02

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:06:02

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:06:02

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:06:02

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58
User entered '0'	System	08 Mar 2021 17:06:02

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58
User entered 'I'	System	08 Mar 2021 17:06:02

US3602004

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:58

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 06:15:01
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with "Yes, subject was assessed for COVID-19 infection on 07-Dec-2020 during an Illness Visit and subsequent Convalescent Period.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 13:11:20
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 06:47:43
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	08 Mar 2021 19:06:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Mar 2021 19:06:40
Data point term sent to Coder	System	08 Mar 2021 18:50:21
User entered 'Shortness of breath'	(b) (4), (b) (6)	08 Mar 2021 18:49:21

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:49:21

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:49:21

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:49:21

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered '3 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:49:21

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:49:21

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00
User entered empty.	System	08 Mar 2021 18:49:21

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:49:21

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered '4 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:49:21

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:49:21

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00
User entered empty.	System	08 Mar 2021 18:49:21

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:49:21

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:49:21

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:49:21

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:49:21

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:49:21

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:49:21

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:49:21

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:49:21

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:49:21

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:49:21

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:49:21

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:49:21

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:49:21

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:49:21

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:49:21

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:49:21

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:49:21

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:49:21

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:49:21

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:49:21

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:39:01
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:49:21

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00
User entered '0'	System	08 Mar 2021 18:49:21

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00
User entered 'I'	System	08 Mar 2021 18:49:21

US3602004

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:08:05

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:55:00

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:08:05

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:46:05
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:50:19
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User closed query 'Per CDM: Per the participant response, medication was taken to treat pain or fever for Day 2 (29 SEP 2020) and Day 7 (04 OCT 2020) on Diary dose 2 mentioned as “during day 8 safety call (09 SEP 2020) subject has informed no medication has taken for soreness”, but day 8 safety call (09 SEP 2020) which was happened very early to the dairy dose 2 (day2- 29 SEP 2020 and day7- 04 OCT 2020) events, kindly review and confirm the participant medication details and record the medication on the concomitant medication pages. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:27:18
Query 'Per CDM: Per the participant response, medication was taken to treat pain or fever for Day 2 (29 SEP 2020) and Day 7 (04 OCT 2020) on Diary dose 2 mentioned as “during day 8 safety call (09 SEP 2020) subject has informed no medication has taken for soreness”, but day 8 safety call (09 SEP 2020) which was happened very early to the dairy dose 2 (day2- 29 SEP 2020 and day7- 04 OCT 2020) events, kindly review and confirm the participant medication details and record the medication on the concomitant medication pages. Thank you.' answered with 'Advil is documented as being taken from 9/2/2020 -9/7/2020, this was what the subject took to treat pain. The subject was called back and this was confirmed. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 13:21:21

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:08:05

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
User opened query 'Per CDM: Per the participant response, medication was taken to treat pain or fever for Day 2 (29 SEP 2020) and Day 7 (04 OCT 2020) on Diary dose 2 mentioned as "during day 8 safety call (09 SEP 2020) subject has informed no medication has taken for soreness", but day 8 safety call (09 SEP 2020) which was happened very early to the dairy dose 2 (day2- 29 SEP 2020 and day7- 04 OCT 2020) events, kindly review and confirm the participant medication details and record the medication on the concomitant medication pages. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 04:28:31
User closed query 'Per CDM: Response noted" Advil was confirmed (by the provider and in EMR) and then documented as being taken in Concaomitant Medication.", for Ediary dose Day 3 (3-sep-2020)and Day 7(7-Sep-2020), however the on concomitant medication page Advil is reported as start and Stop date as 2- Sep-2020.Kindly update the data accordingly .' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:08:48
Query 'Per CDM: Response noted" Advil was confirmed (by the provider and in EMR) and then documented as being taken in Concaomitant Medication.", for Ediary dose Day 3 (3-sep-2020)and Day 7(7-Sep-2020), however the on concomitant medication page Advil is reported as start and Stop date as 2- Sep-2020.Kindly update the data accordingly .' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 13:25:45
User opened query 'Per CDM: Response noted" Advil was confirmed (by the provider and in EMR) and then documented as being taken in Concaomitant Medication.", for Ediary dose Day 3 (3-sep-2020)and Day 7(7-Sep-2020), however the on concomitant medication page Advil is reported as start and Stop date as 2- Sep-2020.Kindly update the data accordingly .' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 07:57:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 13:40:43

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	28 Sep 2020 17:19:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	28 Sep 2020 17:19:45
Data point term sent to Coder	System	28 Sep 2020 17:19:08
Coding entries removed.	(b) (4), (b) (6)	28 Sep 2020 17:18:30
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Sep 2020 13:50:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Sep 2020 13:50:42
Data point term sent to Coder	System	04 Sep 2020 13:49:57
User entered 'Gabapentin'	(b) (4), (b) (6)	04 Sep 2020 13:49:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:49:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Restless Leg Syndrome' reason for change: Data Entry Error	(b) (4)	28 Sep 2020 17:18:30
User entered 'Nerve Pain'	(b) (4), (b) (6)	04 Sep 2020 13:49:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '400'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:49:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:49:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:49:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:49:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:49:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:49:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:49:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:49:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'I'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:49:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:49:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:49:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:49:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	04 Sep 2020 13:49:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 13:49:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 13:49:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Sep 2020 15:08:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 15:08:46
Data point term sent to Coder	System	04 Sep 2020 13:50:59
User entered 'Metformin'	(b) (4), (b) (6)	04 Sep 2020 13:50:36

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:50:36

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'IDDM'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:50:36

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '1000'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:50:36

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:50:36

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:50:36

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:50:36

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:50:36

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:50:36

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:50:36

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:50:36

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'I'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:50:36

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:50:36

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:50:36

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:50:36

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	04 Sep 2020 13:50:36

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 13:50:36

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 13:50:36

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 16:49:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 16:49:22
Data point term sent to Coder Coding entries removed.	System	05 Nov 2020 16:48:39
	(b) (4), (b) (6)	05 Nov 2020 16:48:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 13:55:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 13:55:46
Data point term sent to Coder User entered 'Atorvastatin'	System	04 Sep 2020 13:54:05
	(b) (4), (b) (6)	04 Sep 2020 13:54:04

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:54:04

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:48:15
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 16:48:32
User entered 'HYPERCHOLESTEROLEMIA' reason for change: Per Query Resolution	(b) (4), (b) (6)	05 Nov 2020 16:48:24
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 08:38:13
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	04 Sep 2020 13:54:04

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '40'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:54:04

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:54:04

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:54:04

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:54:04

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:54:04

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:54:04

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:54:04

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:54:04

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'I'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:54:04

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:54:04

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:54:04

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:54:04

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 13:54:04

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 13:54:04

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 13:54:04

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS, PRODUCT: EMPAGLIFLOZIN, PRODUCTSYNONYM: JARDIANCE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Sep 2020 13:56:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 13:56:39
Data point term sent to Coder	System	04 Sep 2020 13:56:08
User entered 'Jardiance'	(b) (4), (b) (6)	04 Sep 2020 13:55:39

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:55:39

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'IDDM'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:55:39

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '10'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:55:39

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:55:39

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:55:39

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:55:39

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:55:39

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:55:39

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:55:39

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:55:39

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'I'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:55:39

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:55:39

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:55:39

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:55:39

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 13:55:39

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 13:55:39

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 13:55:39

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Sep 2020 14:00:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 14:00:41
Data point term sent to Coder	System	04 Sep 2020 13:59:13
User entered 'Loratadine'	(b) (4), (b) (6)	04 Sep 2020 13:58:32

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:58:32

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:52:20
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'Medical condition has been recorded in Med Hx as per query.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 21:48:29
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 08:38:37
User entered 'Seasonal Allergies'	(b) (4), (b) (6)	04 Sep 2020 13:58:32

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '10'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:58:32

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:58:32

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:58:32

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:58:32

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:58:32

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:58:32

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:58:32

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:58:32

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'I'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:58:32

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:58:32

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:58:32

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:58:32

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 13:58:32

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 13:58:32

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 13:58:32

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Nov 2020 06:29:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Nov 2020 06:29:38
Data point term sent to Coder	System	12 Nov 2020 22:09:13
Coding entries removed.	(b) (4), (b) (6)	12 Nov 2020 22:08:50
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Sep 2020 14:01:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Sep 2020 14:01:39
Data point term sent to Coder	System	04 Sep 2020 14:00:16
Data point term sent to Coder	System	04 Sep 2020 13:59:14
User entered 'Ibuprofen'	(b) (4), (b) (6)	04 Sep 2020 13:59:12

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:59:12

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Oral PAIN' reason for change: New Information	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:08:50
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of Pain. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.	(b) (4), (b) (6)	06 Nov 2020 04:48:50
' (Site from DM).		
Query 'Per DM CLR: Please update the indication to reflect the location and type of Pain. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.	(b) (4), (b) (6)	05 Nov 2020 16:56:14
' answered with 'overall pain, ibuprofen is taken PRN		
' (Site from DM).		
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of Pain. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.	(b) (4), (b) (6)	28 Oct 2020 08:38:56
' (Site from DM).		
User entered 'Pain'	(b) (4), (b) (6)	04 Sep 2020 13:59:12

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '400' reason for change: New Information	(b) (4)	12 Nov 2020 22:08:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	04 Sep 2020 13:59:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 13:59:32
User entered 'unknown' reason for change: Data Entry Error	System	04 Sep 2020 13:59:32
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	04 Sep 2020 13:59:12
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 13:59:12

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	04 Sep 2020 13:59:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 13:59:32
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 13:59:32
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 13:59:12
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 13:59:12

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:59:12

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:59:12

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:59:12

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 13:59:32
User entered 'Oral (ORAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 13:59:32
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 13:59:12
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 13:59:12

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:59:12

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'UN UNK 2000' reason for change: New Information	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:08:50
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 13:59:12

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '0' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 22:08:50
User entered '1'	(b) (4), (b) (6)	04 Sep 2020 13:59:12

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:59:12

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:59:12

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:59:12

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 13:59:12

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 13:59:12

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 13:59:12

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 03:31:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 03:31:15
Data point term sent to Coder	System	13 Nov 2020 21:49:47
Coding entries removed.	(b) (4), (b) (6)	13 Nov 2020 21:49:11
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 08:51:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 08:51:52
Data point term sent to Coder	System	28 Sep 2020 17:18:05
Data point term sent to Coder	System	14 Sep 2020 16:08:29
User closed query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	System	14 Sep 2020 16:08:16
Query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' answered with 'Per EMR patient is using Doterra oil' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 16:08:16

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	07 Sep 2020 13:00:41
Data point term sent to Coder	System	04 Sep 2020 14:01:17
User entered 'Doterra Oil'	(b) (4), (b) (6)	04 Sep 2020 14:00:23

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:00:23

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 16:51:23
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'Condition has been recorded in Med Hx eCRF.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 21:49:40
User entered 'ANTI-REFLUX (for self-diagnosed GERD)' reason for change: New Information	(b) (4), (b) (6)	13 Nov 2020 21:49:11
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' canceled (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 08:39:51
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 08:39:34
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 13:22:27
User entered 'Anti-Reflux' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 17:18:01
User entered 'Anxiety'	(b) (4), (b) (6)	04 Sep 2020 14:00:23

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EAB) (1725)

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US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'I'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:00:23

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:49:05
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'per emr, doterra oil is taken in tablet form' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 16:55:10
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 08:40:05
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	04 Sep 2020 14:00:23

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:00:23

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:00:23

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:00:23

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:00:23

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:00:23

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:00:23

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'I'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:00:23

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:00:23

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:00:23

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:00:23

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 14:00:23

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 14:00:23

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 14:00:23

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: CANNABIS SATIVA, PRODUCTSYNONYM: HEMP - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 14:42:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 14:42:13
Data point term sent to Coder	System	13 Nov 2020 21:51:50
Coding entries removed.	(b) (4), (b) (6)	13 Nov 2020 21:50:55
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CANNABIS SATIVA, PRODUCTSYNONYM: HEMP - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 11:07:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 11:07:54
Data point term sent to Coder	System	28 Sep 2020 17:18:05
Coding entries removed.	(b) (4), (b) (6)	28 Sep 2020 17:17:46
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CANNABIS SATIVA, PRODUCTSYNONYM: HEMP - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Sep 2020 15:03:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Sep 2020 15:03:44
Data point term sent to Coder	System	04 Sep 2020 14:02:21
User entered 'Hemp Extract'	(b) (4), (b) (6)	04 Sep 2020 14:01:23

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:01:23

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:55:48
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'Condition has been recorded in Med Hx eCRF.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 21:51:03
User entered 'SLEEP AIDE (for self-diagnosed Insomnia)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 21:50:55
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 13:22:45
User entered 'Sleep Aide' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 17:17:46
User entered 'Anxiety'	(b) (4), (b) (6)	04 Sep 2020 14:01:23

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'I'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:01:23

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:49:11
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'EMR states Tablet' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 16:50:50
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 08:40:30
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	04 Sep 2020 14:01:23

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:01:23

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:01:23

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:01:23

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:01:23

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:01:23

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'UN Jul 2020' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 16:50:26
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 14:01:23

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '0' reason for change: New Information	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:50:26
User entered '1'	(b) (4), (b) (6)	04 Sep 2020 14:01:23

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:01:23

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:01:23

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:01:23

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 14:01:23

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 14:01:23

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 14:01:23

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: BERBERINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 22:27:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 22:27:43
Data point term sent to Coder	System	28 Sep 2020 17:18:02
Coding entries removed.	(b) (4), (b) (6)	28 Sep 2020 17:17:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: BERBERINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 14:37:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 14:37:34
Data point term sent to Coder	System	04 Sep 2020 14:03:22
User entered 'Berberine'	(b) (4), (b) (6)	04 Sep 2020 14:02:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:02:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Glycemic Control' reason for change:	(b) (4)	
Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 17:17:31
User entered 'Vitamin Supplement'	(b) (4), (b) (6)	04 Sep 2020 14:02:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '600'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:02:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:02:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:02:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:02:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:02:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:02:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:02:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:02:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'I'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:02:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:02:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:02:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:02:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 14:02:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 14:02:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 14:02:35

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Sep 2020 14:09:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 14:09:45
Data point term sent to Coder	System	04 Sep 2020 14:08:26
User entered 'Advil'	(b) (4), (b) (6)	04 Sep 2020 14:08:09

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:08:09

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 05:00:24
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' answered with 'The pain occurred during diary reporting, Pain at injection site is a solicited AE and did not need to be reported in AE log.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 16:42:13

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM). User entered 'Pain at Injection site'	(b) (4), (b) (6) (b) (4), (b) (6)	27 Oct 2020 13:23:16
	(b) (4), (b) (6)	04 Sep 2020 14:08:09

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '2'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:08:09

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:08:09

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:08:09

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:08:09

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'for this one event'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:08:09

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:08:09

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:08:09

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '2 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:08:09

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:08:09

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:08:09

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '7 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 13:26:05
User entered '2 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 14:08:09

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:02
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:08:09

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:02
User entered empty.	System	04 Sep 2020 14:08:09

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:02
User entered empty.	System	04 Sep 2020 14:08:09

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:02
User entered empty.	System	04 Sep 2020 14:08:09

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:05
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:05:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Dec 2020 19:14:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Dec 2020 19:14:08
Data point term sent to Coder	System	07 Dec 2020 18:29:02
User entered 'Advil'	(b) (4), (b) (6)	07 Dec 2020 18:28:10

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:05
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:05:50
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:28:10

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:05
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:05:53
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Headache and Congestion'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:28:10

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:05
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:05:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '400' reason for change: New Information	(b) (4), (b) (6)	09 Dec 2020 17:17:21
User entered '2'	(b) (4), (b) (6)	07 Dec 2020 18:28:10

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:05
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:05:57
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'mg (mg)' reason for change: New Information	(b) (4), (b) (6)	09 Dec 2020 17:17:21
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	07 Dec 2020 18:28:10

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:05
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:05:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:28:10

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:05
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:06:02
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:28:10

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:05
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:06:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:28:10

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:05
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:06:06
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:28:10

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:05
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:06:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:28:10

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:05
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:06:11
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '04 Dec 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:28:10

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:05
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:06:13
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:28:10

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:05
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:06:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	15 Dec 2020 15:38:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Dec 2020 18:28:10

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:05
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:06:16
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '09 Dec 2020' reason for change: New Information	(b) (4), (b) (6)	15 Dec 2020 15:38:21
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 18:28:10

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:05
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:06:18
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:28:10

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:05
User entered '2'	System	07 Dec 2020 18:28:10

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:05
User entered '1'	System	07 Dec 2020 18:28:10

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:05
User entered '804 (804)'	System	07 Dec 2020 18:28:10

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:09
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: SUDAFED [PSEUDOEPHEDRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 11:26:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 11:26:30
Data point term sent to Coder	System	31 Mar 2021 16:48:57
Coding entries removed.	(b) (4), (b) (6)	31 Mar 2021 16:48:55
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: SUDAFED [PSEUDOEPHEDRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 11:08:51
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 Mar 2021 11:08:51
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:54:00
Data point term sent to Coder	System	26 Feb 2021 21:10:28
Coding entries removed.	(b) (4), (b) (6)	26 Feb 2021 21:09:59
User signature succeeded.	Bindu Balani (b) (4) (b) (4)	19 Feb 2021 22:06:21
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: SUDAFED [PSEUDOEPHEDRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Dec 2020 01:54:50

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US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder	Coder Import (b) (4) (b) (4) System	19 Dec 2020 01:54:50 15 Dec 2020 15:44:48
User entered 'Sudafed OTC (Pseudoephedrine HCl)'	(b) (4), (b) (6)	15 Dec 2020 15:44:07

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:09
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:54:00
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:44:07

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:09
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:48:55
User entered 'Upper respiratory tract infection' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 16:48:55
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:54:00
Signature has been broken.	(b) (4), (b) (6)	26 Feb 2021 21:09:59
User entered 'Right SINUS CONGESTION' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 21:09:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User closed query 'Per DM CLR: Please note there is no ongoing AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 02:40:41
Query 'Per DM CLR: Please note there is no ongoing AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' answered with 'the indication is documented in the symptom log under covid-19 assesments.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 15:54:06
User opened query 'Per DM CLR: Please note there is no ongoing AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 11:28:47
User entered 'Sinus Congestion'	(b) (4), (b) (6)	15 Dec 2020 15:44:07

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:09
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:54:00
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '30'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:44:07

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:09
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:54:00
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:44:07

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:09
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:54:00
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:44:07

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:09
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User closed query 'Per DM CLR: Please review the frequency and confirm if this should be changed/updated to 'once' as the Medication was given for 1 day duration only. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 14:01:56
Query 'Per DM CLR: Please review the frequency and confirm if this should be changed/updated to 'once' as the Medication was given for 1 day duration only. Update eCRF as appropriate.' answered with 'Frequency updated to "once" as per progress notes.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 13:58:27
DataPoint Un-verified.	(b) (4), (b) (6)	17 Mar 2021 13:56:31
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 13:56:31
User entered 'once (ONCE)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 13:56:31
User opened query 'Per DM CLR: Please review the frequency and confirm if this should be changed/updated to 'once' as the Medication was given for 1 day duration only. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 11:31:08
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:54:00
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:44:07

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:09
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:54:00
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:44:07

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:09
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:54:00
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:44:07

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:09
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:54:00
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:44:07

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:09
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:54:00
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '10 Dec 2020'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:44:07

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:09
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:54:00
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:44:07

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:09
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:54:00
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:44:07

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:09
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:54:00
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '10 Dec 2020'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:44:07

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:09
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:54:00
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:44:07

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:09
User entered empty.	System	17 Mar 2021 13:56:31
User entered '1'	System	15 Dec 2020 15:44:07

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:09
User entered empty.	System	17 Mar 2021 13:56:31
User entered '1'	System	15 Dec 2020 15:44:07

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:09
User entered empty.	System	17 Mar 2021 13:56:31
User entered '804 (804)'	System	15 Dec 2020 15:44:07

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:11
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 09:55:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 09:55:28
Data point term sent to Coder	System	31 Mar 2021 16:49:58
Coding entries removed.	(b) (4), (b) (6)	31 Mar 2021 16:49:25
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:58:41
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 10:58:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 10:58:11
Data point term sent to Coder	System	26 Feb 2021 21:04:20
Coding entries removed.	(b) (4), (b) (6)	26 Feb 2021 21:04:15
User signature succeeded.	Bindu Balani (b) (4) (b) (4)	19 Feb 2021 22:06:21

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 19:14:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 19:14:53
Data point term sent to Coder	System	15 Dec 2020 15:45:49
User entered 'Flonase (Fluticasone)'	(b) (4), (b) (6)	15 Dec 2020 15:45:30

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:58:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:45:30

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:11
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:49:25
User entered 'Upper respiratory tract infection' reason for change: New Information	(b) (4), (b) (6)	31 Mar 2021 16:49:25
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:58:45
Signature has been broken.	(b) (4), (b) (6)	26 Feb 2021 21:04:15
User entered 'Right SINUS CONGESTION' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 21:04:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User closed query 'Per DM CLR: Please note there is no ongoing AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 02:40:54
Query 'Per DM CLR: Please note there is no ongoing AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' answered with 'the indication is documented in the symptom log under covid-19 assesments.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 15:54:12
User opened query 'Per DM CLR: Please note there is no ongoing AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 12:13:31
User entered 'Sinus Congestion'	(b) (4), (b) (6)	15 Dec 2020 15:45:30

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:58:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User closed query 'Per DM CLR: Please provide the actual dose of this medication in this field, as well as to review the dose unit that correspond to available dose (e.g. dose=50 ; unit=ug). Please update dose and dose unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 02:40:52
Query 'Per DM CLR: Please provide the actual dose of this medication in this field, as well as to review the dose unit that correspond to available dose (e.g. dose=50 ; unit=ug). Please update dose and dose unit fields as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 15:55:01
User entered '100' reason for change: Per Query Resolution	(b) (4), (b) (6)	27 Jan 2021 15:54:57
User opened query 'Per DM CLR: Please provide the actual dose of this medication in this field, as well as to review the dose unit that correspond to available dose (e.g. dose=50 ; unit=ug). Please update dose and dose unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 12:10:39
User entered 'other'	(b) (4), (b) (6)	15 Dec 2020 15:45:30

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:58:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'ug (ug)' reason for change: Per Query Resolution	(b) (4)	27 Jan 2021 15:54:57
User entered 'Other (OTHER)'	(b) (4), (b) (6)	15 Dec 2020 15:45:30

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:58:53
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	27 Jan 2021 15:54:57
User entered '2 sprays, 50 mcg each'	(b) (4), (b) (6)	15 Dec 2020 15:45:30

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:58:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:45:30

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:58:57
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:45:30

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:59:00
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'Nasal (NASAL)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:45:30

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:59:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:45:30

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:59:06
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding MH. Please review and reconcile Con Med and MH start/stop dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 20:49:12
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding MH. Please review and reconcile Con Med and MH start/stop dates as appropriate. Otherwise, clarify. ' answered with 'As per data clarification in 11-Dec-2020 progress notes, AE "Right sinus congestion" resolved on 11-Dec-2020 and AE stop date has been updated in EDC.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 21:07:03
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding MH. Please review and reconcile Con Med and MH start/stop dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 16:46:18
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '10 Dec 2020'	(b) (4), (b) (6)	15 Dec 2020 15:45:30

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:59:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:45:30

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:59:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:45:30

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:11
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:47:41
User closed query 'Progress note indicated subject took Sudafed OTC Pseudoephedrine HCL and Flonase (Fluticasone) Nasal Spray on 12/10/20. The end date for Sudafed OTC Pseudoephedrine HCL was 12/10/20. Verify if end date for Flonase should be 12/10/20 and update date accordingly.' (Site from CRA).	(b) (4), (b) (6)	11 Mar 2021 14:47:39
Query 'Progress note indicated subject took Sudafed OTC Pseudoephedrine HCL and Flonase (Fluticasone) Nasal Spray on 12/10/20. The end date for Sudafed OTC Pseudoephedrine HCL was 12/10/20. Verify if end date for Flonase should be 12/10/20 and update date accordingly.' answered with 'Confirming ConMed end date was 10-Dec-2020. Data has been updated accordingly.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 14:10:53
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 14:10:03
User entered '10 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 14:10:03
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User opened query 'Progress note indicated subject took Sudafed OTC Pseudoephedrine HCL and Flonase (Fluticasone) Nasal Spray on 12/10/20. The end date for Sudafed OTC Pseudoephedrine HCL was 12/10/20. Verify if end date for Flonase should be 12/10/20 and update date accordingly.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 23:58:36
Signature has been broken.	(b) (4), (b) (6)	25 Feb 2021 17:10:48
User entered '11 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 17:10:48
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered '10 Dec 2020'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:45:30

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US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:59:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:45:30

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:11
User entered '1'	System	15 Dec 2020 15:45:30

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:11
User entered '1'	System	15 Dec 2020 15:45:30

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:11
User entered '804 (804)'	System	15 Dec 2020 15:45:30

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 00:36:05
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: ASA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 20:11:02
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 20:11:02
	(b) (4)	
Data point term sent to Coder	System	25 Feb 2021 21:25:50
User entered 'ASA (Aspirin)'	(b) (4), (b) (6)	25 Feb 2021 21:25:18

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Feb 2021 21:25:18

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered 'NSTEMI (Non-ST Segment Elevated Myocardial Infarction)'	(b) (4), (b) (6)	25 Feb 2021 21:25:18

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered '81'	(b) (4), (b) (6)	25 Feb 2021 21:25:18

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Feb 2021 21:25:18

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 21:25:18

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered 'once daily (QD)'	(b) (4), (b) (6)	25 Feb 2021 21:25:18

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 21:25:18

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Feb 2021 21:25:18

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 21:25:18

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered '4 Jan 2021'	(b) (4), (b) (6)	25 Feb 2021 21:25:18

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 21:25:18

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Feb 2021 21:25:18

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 21:25:18

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 21:25:18

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 21:25:18

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 21:25:18

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Feb 2021 21:25:18

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:18
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROSTAT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 11:50:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 11:50:41
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
Data point term sent to Coder System	System	25 Feb 2021 21:30:55
User entered 'Nitroglycerin (Nitrostat) tablet'	(b) (4), (b) (6)	25 Feb 2021 21:30:15

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:18
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 21:30:15

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:18
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered 'NSTEMI (Non-ST Segment Elevation Myocardial Infarction)'	(b) (4), (b) (6)	25 Feb 2021 21:30:15

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:18
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User closed query 'Per CDM Re-Query: Please follow CRF Guidelines for unknown (UNK) doses. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 04:57:53
Query 'Per CDM Re-Query: Please follow CRF Guidelines for unknown (UNK) doses. Thank you' answered with 'Dose updated as per query.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 18:54:43
DataPoint Un-verified.	(b) (4), (b) (6)	18 Mar 2021 18:54:25
User entered 'UNK' reason for change: Per Query Resolution	(b) (4), (b) (6)	18 Mar 2021 18:54:25
User opened query 'Per CDM Re-Query: Please follow CRF Guidelines for unknown (UNK) doses. Thank you' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 14:22:57
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 14:22:57
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate.' answered with 'Subject reported that they "did not recall" ConMed dosage and ConMed dosage was not documented on released MR's.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 14:08:39
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 11:32:08
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered 'I'	(b) (4), (b) (6)	25 Feb 2021 21:30:15

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:18
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 18:55:10
User entered 'mg (mg)' reason for change: Per Query Resolution	(b) (4), (b) (6)	18 Mar 2021 18:55:10
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	25 Feb 2021 21:30:15

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:18
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 21:30:15

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:18
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered 'once (ONCE)'	(b) (4), (b) (6)	25 Feb 2021 21:30:15

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:18
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 21:30:15

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:18
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered 'Other (OTHER)'	(b) (4), (b) (6)	25 Feb 2021 21:30:15

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:18
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered 'Sublingual'	(b) (4), (b) (6)	25 Feb 2021 21:30:15

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:18
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered '4 Jan 2021'	(b) (4), (b) (6)	25 Feb 2021 21:30:15

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:18
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 21:30:15

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:18
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 21:30:15

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:18
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered '4 Jan 2021'	(b) (4), (b) (6)	25 Feb 2021 21:30:15

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:18
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 21:30:15

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:18
User entered empty.	System	25 Feb 2021 21:30:15

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:18
User entered empty.	System	25 Feb 2021 21:30:15

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:18
User entered empty.	System	25 Feb 2021 21:30:15

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:08:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:22
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL TARTRATE, PRODUCTSYNONYM: LOPRESSOR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Mar 2021 22:39:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Mar 2021 22:39:54
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
Data point term sent to Coder User entered 'Lopressor (Metoprolol Tartrate)'	System (b) (4), (b) (6)	25 Feb 2021 21:32:57 25 Feb 2021 21:32:54

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:22
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 21:32:54

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:22
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered 'NSTEMI (Non-ST Segment Elevation Myocardial Infarction)'	(b) (4), (b) (6)	25 Feb 2021 21:32:54

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:22
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User closed query 'Per CDM Re-Query: Please follow CRF Guidelines for unknown (UNK) doses. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 04:58:01
Query 'Per CDM Re-Query: Please follow CRF Guidelines for unknown (UNK) doses. Thank you' answered with 'Dose has been updated as per query.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 18:56:25
DataPoint Un-verified.	(b) (4), (b) (6)	18 Mar 2021 18:56:06
User entered 'UNK' reason for change: Per Query Resolution	(b) (4), (b) (6)	18 Mar 2021 18:56:06
User opened query 'Per CDM Re-Query: Please follow CRF Guidelines for unknown (UNK) doses. Thank you' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 13:58:34
User closed query 'Per DM CLR: Please provide the actual dose for this medication in Milligrams instead of number of Course as there are other dosage options for this drug. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 13:58:34
Query 'Per DM CLR: Please provide the actual dose for this medication in Milligrams instead of number of Course as there are other dosage options for this drug. Update Con Med eCRF as appropriate.' answered with 'As per progress notes, subject reported that they "did not recall" actual ConMed dosage and ConMed dosage was not documented in released MR's.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 14:10:27
User opened query 'Per DM CLR: Please provide the actual dose for this medication in Milligrams instead of number of Course as there are other dosage options for this drug. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 11:33:09
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 21:36:45
User entered 'UNK'	(b) (4), (b) (6)	25 Feb 2021 21:32:54

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:22
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered 'Other (OTHER)'	(b) (4), (b) (6)	25 Feb 2021 21:32:54

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:08:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:22
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 18:56:06
User entered 'Unknown' reason for change: Per Query Resolution	(b) (4), (b) (6)	18 Mar 2021 18:56:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered 'Course' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 21:36:45
User entered 'UNK'	(b) (4), (b) (6)	25 Feb 2021 21:32:54

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:22
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered 'once (ONCE)'	(b) (4), (b) (6)	25 Feb 2021 21:32:54

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:08:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:22
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 21:32:54

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:22
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4), (b) (6)	25 Feb 2021 21:32:54

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:08:05

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:22
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 21:32:54

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:22
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered '4 Jan 2021'	(b) (4), (b) (6)	25 Feb 2021 21:32:54

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:22
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 21:32:54

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:22
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 21:32:54

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:22
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered '4 Jan 2021'	(b) (4), (b) (6)	25 Feb 2021 21:32:54

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:08:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:22
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:36:05
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 21:32:54

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:22
User entered empty.	System	25 Feb 2021 21:32:54

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:22
User entered empty.	System	25 Feb 2021 21:32:54

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:22
User entered empty.	System	25 Feb 2021 21:32:54

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:08:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:26
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 18:53:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	08 Mar 2021 18:53:01
Data point term sent to Coder	System	08 Mar 2021 18:52:23
User entered 'Albuterol'	(b) (4), (b) (6)	08 Mar 2021 18:51:47

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:26
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:47

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:26
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered 'Shortness of breath'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:47

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:26
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered '180'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:47

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:26
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered 'ug (ug)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:47

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:08:05

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:26
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:47

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:26
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	08 Mar 2021 18:52:20
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	08 Mar 2021 18:52:20
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	08 Mar 2021 18:51:47
User entered 'once (ONCE)'	(b) (4), (b) (6)	08 Mar 2021 18:51:47

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:08:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:26
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:47

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:26
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:47

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:08:05

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:26
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:47

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:26
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered '3 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:47

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:26
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:47

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:26
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:47

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:26
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered '3 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	08 Mar 2021 18:52:20
User entered '4 Jan 2021'	(b) (4), (b) (6)	08 Mar 2021 18:51:47

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:08:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:26
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 18:51:47

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:26
User entered empty.	System	08 Mar 2021 18:51:47

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:26
User entered empty.	System	08 Mar 2021 18:51:47

US3602004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:10:26
User entered empty.	System	08 Mar 2021 18:51:47

US3602004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:08:05

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:46:05
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
Signature has been broken.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:37:09
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 21:37:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:23:35

US3602004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:08:05

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
	(b) (4)	
User entered '4 Jan 2021'	(b) (4), (b) (6)	25 Feb 2021 21:38:03

US3602004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:08:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered 'EKG'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:38:03

US3602004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:38:03

US3602004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:08:05

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 21:38:03

US3602004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:08:05

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:42:27
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered '4 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:24:05

US3602004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:08:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:42:27
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered 'Left Heart Catheterization'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:24:05

US3602004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:42:27
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:24:05

US3602004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:08:05

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:42:27
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:24:05

US3602004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:08:05

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:42:32
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered '4 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:04:08

US3602004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:08:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:42:32
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered 'Blood Work-Up'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:04:08

US3602004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:42:32
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:04:08

US3602004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:08:05

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:42:32
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:04:08

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'USA-US079-2021-MRNA-1273-P301000003'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'Yes (Y)'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'No (N)'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'No (N)'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'Yes (Y)'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'No (N)'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'No (N)'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'No (N)'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'Bindu'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'Balani'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 14:27:05
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:59
Un-reviewed for Safety.	System	04 Mar 2021 15:23:14
User entered empty.	System	04 Mar 2021 15:23:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:23:03
User entered '20 Prospect Avenue'	(b) (4), (b) (6)	26 Feb 2021 20:59:28

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 14:27:05
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:59
Un-reviewed for Safety.	System	04 Mar 2021 15:23:14
User entered empty.	System	04 Mar 2021 15:23:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:23:03
User entered 'Hackensack'	(b) (4), (b) (6)	26 Feb 2021 20:59:28

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'NJ'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 14:27:05
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:59
Un-reviewed for Safety.	System	04 Mar 2021 15:23:14
User entered empty.	System	04 Mar 2021 15:23:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:23:03
User entered '07601'	(b) (4), (b) (6)	26 Feb 2021 20:59:28

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'US'	System	26 Feb 2021 16:19:49

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	05 Mar 2021 14:27:35
User entered '2'	System	04 Mar 2021 15:23:14
User entered '1'	System	26 Feb 2021 16:19:49

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'USA-US079-2021-MRNA-1273-P301000003'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'Yes (Y)'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'No (N)'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'No (N)'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'Yes (Y)'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'No (N)'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'No (N)'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'No (N)'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'Bindu'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'Balani'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 14:27:05
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:59
Un-reviewed for Safety.	System	04 Mar 2021 15:23:14
User entered empty.	System	04 Mar 2021 15:23:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:23:03
User entered '20 Prospect Avenue'	(b) (4), (b) (6)	26 Feb 2021 20:59:28

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 14:27:05
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:59
Un-reviewed for Safety.	System	04 Mar 2021 15:23:14
User entered empty.	System	04 Mar 2021 15:23:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:23:03
User entered 'Hackensack'	(b) (4), (b) (6)	26 Feb 2021 20:59:28

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'NJ'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 14:27:05
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:59
Un-reviewed for Safety.	System	04 Mar 2021 15:23:14
User entered empty.	System	04 Mar 2021 15:23:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:23:03
User entered '07601'	(b) (4), (b) (6)	26 Feb 2021 20:59:28

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'US'	System	26 Feb 2021 16:19:49

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	05 Mar 2021 14:27:35
User entered '2'	System	04 Mar 2021 15:23:14
User entered '1'	System	26 Feb 2021 16:19:49

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:08:05

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
User entered '26/Feb/2021 10:19'	System	26 Feb 2021 16:19:49

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:08:05

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'I'	(b) (4), (b) (6)	26 Feb 2021 16:19:49

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'USA-US079-2021-MRNA-1273-P301000003'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'Yes (Y)'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'No (N)'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'No (N)'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'Yes (Y)'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'No (N)'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'No (N)'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'No (N)'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'Bindu'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'Balani'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 14:27:05
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:59
Un-reviewed for Safety.	System	04 Mar 2021 15:23:14
User entered empty.	System	04 Mar 2021 15:23:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:23:03
User entered '20 Prospect Avenue'	(b) (4), (b) (6)	26 Feb 2021 20:59:28

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 14:27:05
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:59
Un-reviewed for Safety.	System	04 Mar 2021 15:23:14
User entered empty.	System	04 Mar 2021 15:23:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:23:03
User entered 'Hackensack'	(b) (4), (b) (6)	26 Feb 2021 20:59:28

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'NJ'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 14:27:05
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:59
Un-reviewed for Safety.	System	04 Mar 2021 15:23:14
User entered empty.	System	04 Mar 2021 15:23:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:23:03
User entered '07601'	(b) (4), (b) (6)	26 Feb 2021 20:59:28

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'US'	System	26 Feb 2021 16:19:49

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	05 Mar 2021 14:27:35
User entered '2'	System	04 Mar 2021 15:23:14
User entered '1'	System	26 Feb 2021 16:19:49

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:08:05

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
User entered '04/Mar/2021 10:23'	System	04 Mar 2021 15:23:14

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:08:05

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 14:27:05
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:59
User entered 'I'	(b) (4), (b) (6)	04 Mar 2021 15:23:14

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'USA-US079-2021-MRNA-1273-P301000003'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'Yes (Y)'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'No (N)'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'No (N)'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'Yes (Y)'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'No (N)'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'No (N)'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'No (N)'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'Bindu'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'Balani'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 14:27:05
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:59
Un-reviewed for Safety.	System	04 Mar 2021 15:23:14
User entered empty.	System	04 Mar 2021 15:23:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:23:03
User entered '20 Prospect Avenue'	(b) (4), (b) (6)	26 Feb 2021 20:59:28

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 14:27:05
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:59
Un-reviewed for Safety.	System	04 Mar 2021 15:23:14
User entered empty.	System	04 Mar 2021 15:23:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:23:03
User entered 'Hackensack'	(b) (4), (b) (6)	26 Feb 2021 20:59:28

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'NJ'	System	26 Feb 2021 16:19:36

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 14:27:05
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:19:59
Un-reviewed for Safety.	System	04 Mar 2021 15:23:14
User entered empty.	System	04 Mar 2021 15:23:14
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:23:03
User entered '07601'	(b) (4), (b) (6)	26 Feb 2021 20:59:28

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:19:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:19:53
User entered 'US'	System	26 Feb 2021 16:19:49

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	05 Mar 2021 14:27:35
User entered '2'	System	04 Mar 2021 15:23:14
User entered '1'	System	26 Feb 2021 16:19:49

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:08:05

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:18:23
User signature succeeded.	(b) (4), (b) (6)	05 Apr 2021 20:56:02
User entered '05/Mar/2021 09:27'	System	05 Mar 2021 14:27:35

US3602004

Folder: SAE USA-US079-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:08:05

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:18:23
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:02
User entered 'I'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 14:27:35