

US3632127 (Prod: Grady Health System)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:08:05

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US3632127

Form: Participant Creation

Data signed: (b) (4) 05 Apr 2021 01:17:34

Generated On: 10 Jun 2021 09:08:05

[Participant ID](#)

US3632127

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

US3632127

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Mar 2021 12:22:47

Generated On: 10 Jun 2021 09:08:05

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 13 OCT 2020

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

Folder OID SCRN

US3632127

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Mar 2021 12:22:47

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	False
Black	True
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

US3632127

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Mar 2021 12:22:47

Generated On: 10 Jun 2021 09:08:05

Date of Informed Consent (*dd MMM yyyy*) 13 OCT 2020

Month and Year of Informed Consent (derived) OCT 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

US3632127

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Mar 2021 12:22:47

Generated On: 10 Jun 2021 09:08:05

Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Mar 2021 12:22:47

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 Mar 2021 12:22:47

Generated On: 10 Jun 2021 09:08:05

Condition	GEODON ALLERGY (ANAPHYLAXIS)
Start date (dd MMM yyyy)	1 UNK 1993
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 1993
Start Year (derived)	1993
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3632127

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Mar 2021 12:22:47

Generated On: 10 Jun 2021 09:08:05

Condition	HYPERTENSION
Start date (dd MMM yyyy)	1 UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Mar 2021 12:22:47

Generated On: 10 Jun 2021 09:08:05

Condition	OSTEOARTHRITIS
Start date (dd MMM yyyy)	1 UNK 2003
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 2003
Start Year (derived)	2003
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3632127

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Mar 2021 12:22:47

Generated On: 10 Jun 2021 09:08:05

Condition	RHEUMATOID ARTHRITIS (BOTH ANKLES)
Start date (dd MMM yyyy)	1 UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Mar 2021 12:22:47

Generated On: 10 Jun 2021 09:08:05

Condition	HERPES SIMPLEX VIRUS
Start date (dd MMM yyyy)	1 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)	_____

US3632127

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Mar 2021 12:22:47

Generated On: 10 Jun 2021 09:08:05

Condition	SMALL BOWEL SURGERY
Start date (dd MMM yyyy)	1 UNK 1994
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	1 UNK 1994
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1994
Start Year (derived)	1994
Stop Month and Year (derived)	JAN 1994
Stop Year (derived)	1994

US3632127

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Mar 2021 12:22:47

Generated On: 10 Jun 2021 09:08:05

Condition	SMALL BOWEL REPAIR DUE TO BLOCKAGE
Start date (dd MMM yyyy)	1 UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	1 UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Mar 2021 12:22:47

Generated On: 10 Jun 2021 09:08:05

Condition	CONSTIPATION
Start date (dd MMM yyyy)	1 UNK 1994
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 1994
Start Year (derived)	1994
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Mar 2021 12:22:47

Generated On: 10 Jun 2021 09:08:05

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	1 UNK 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3632127

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 15 Mar 2021 12:22:47

Generated On: 10 Jun 2021 09:08:05

Condition	SEVERE OBESITY (BMI 42.13479)
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3632127

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 15 Mar 2021 12:22:47

Generated On: 10 Jun 2021 09:08:05

Condition	ELEVATED CHOLESTEROL
Start date (dd MMM yyyy)	UN FEB 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)	FEB 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3632127

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Mar 2021 12:22:50

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>)	13 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	12:09 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 12:09
Height (<i>xxx.x</i>)	64.5 in
Weight (<i>xxx.x</i>)	248.8 lb
BMI (<i>xxx.x</i>)	42.13479 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Mar 2021 12:22:47

Generated On: 10 Jun 2021 09:08:05

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

13 OCT 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Mar 2021 12:22:46

Generated On: 10 Jun 2021 09:08:05

Date of assessment (*dd MMM yyyy*) 13 OCT 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*) 01 UNK 2006

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Apr 2021 01:37:15

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 HOME HEALTHCARE WORKER

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) 12 Apr 2021 01:37:15

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)	True
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	True
Specify	RESIDENT IN A COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION- 4 ROOM HOUSE

US3632127

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 08 Mar 2021 14:44:28

Generated On: 10 Jun 2021 09:08:05

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 13 OCT 2020

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

Folder OID VISIT1

US3632127

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 08 Mar 2021 14:44:28

Generated On: 10 Jun 2021 09:08:05

What was the date of randomization? (dd MMM yyyy) 13 OCT 2020

What was the participant's randomization number? 146895

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

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

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

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

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

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

Liver Disease Yes No

Human Immunodeficiency Virus (HIV) infection Yes No

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 08 Mar 2021 14:44:28

Generated On: 10 Jun 2021 09:08:05

Height	ND - Not Done
Weight	ND - Not Done

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Mar 2021 14:44:28

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 (<i>dd MMM yyyy</i>)	13 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	12:09 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 12:09
Temperature (<i>xxx.x</i>)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	72 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Mar 2021 14:44:28

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 (<i>dd MMM yyyy</i>)	13 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	14:40 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 14:40
Temperature (<i>xxx.x</i>)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	70 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3632127

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 08 Mar 2021 14:44:28

Generated On: 10 Jun 2021 09:08:05

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

13 OCT 2020

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

US3632127

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 08 Mar 2021 14:44:28

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) 13 OCT 2020

What was the treatment time? (00:00-23:59) 14:10 (24 HR)

Treatment Date and Time (derived) 13 OCT 2020 14:10

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

US3632127

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Mar 2021 14:44:28

Generated On: 10 Jun 2021 09:08:05

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 13 OCT 2020

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

Collection date and time (derived) 13 OCT 2020 12:59

US3632127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 08 Mar 2021 14:44:28

Generated On: 10 Jun 2021 09:08:05

Collection date (<i>dd MMM yyyy</i>)			13 OCT 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:06	13 OCT 2020 13:06
Nasopharyngeal Swab 2	No		

US3632127

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:44:28

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3632127

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 13 OCT 2020 14:41

PC Open Date & Time 13 OCT 2020 14:30

PC Close Date & Time 13 OCT 2020 17:00

US3632127

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 99.3 °F

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

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

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

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

PC Time Stamp 13 OCT 2020 19:37

PC Open Date & Time 13 OCT 2020 17:55

PC Close Date & Time 14 OCT 2020 11:59

US3632127

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	98.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	14 OCT 2020 18:59
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

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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	97.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	15 OCT 2020 18:13
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3632127

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** 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 16 OCT 2020 19:03

PC Open Date & Time 16 OCT 2020 12:00

PC Close Date & Time 17 OCT 2020 11:59

US3632127

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	99.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	17 OCT 2020 18:20
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3632127

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	99.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	18 OCT 2020 18:10
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3632127

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	19 OCT 2020 18:20
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3632127

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.**
Please select one response below

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

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

- Yes
- No

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

- Yes
- No

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**
Please select one response below

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

PC Time Stamp

13 OCT 2020 14:42

PC Open Date & Time

13 OCT 2020 14:30

PC Close Date & Time

13 OCT 2020 17:00

US3632127

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

13 OCT 2020 19:38

PC Open Date & Time

13 OCT 2020 17:55

PC Close Date & Time

14 OCT 2020 11:59

US3632127

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.**

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	14 OCT 2020 19:00
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3632127

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.**

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

15 OCT 2020 18:13

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3632127

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.**

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

16 OCT 2020 19:03

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3632127

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.**

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

17 OCT 2020 18:21

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3632127

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.**

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

18 OCT 2020 18:11

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3632127

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.**

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

19 OCT 2020 18:21

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3632127

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

US3632127

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	13 OCT 2020 14:43
PC Open Date & Time	13 OCT 2020 14:30
PC Close Date & Time	13 OCT 2020 17:00

US3632127

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

US3632127

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	13 OCT 2020 19:39
PC Open Date & Time	13 OCT 2020 17:55
PC Close Date & Time	14 OCT 2020 11:59

US3632127

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

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

	Yes <input type="checkbox"/>
PC Time stamp	14 OCT 2020 19:00
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3632127

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

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

	Yes <input type="checkbox"/>
PC Time stamp	15 OCT 2020 18:14
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3632127

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

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

	Yes <input type="checkbox"/>
PC Time stamp	16 OCT 2020 19:04
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3632127

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

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

	Yes <input type="checkbox"/>
PC Time stamp	17 OCT 2020 18:21
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3632127

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

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

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

US3632127

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

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

	Yes <input type="checkbox"/>
PC Time stamp	19 OCT 2020 18:21
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3632127

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

None

ACHES ALL OVER BODY

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time stamp 20 OCT 2020 14:20

PC Open Date & Time 20 OCT 2020 12:00

PC Close Date & Time 21 OCT 2020 11:59

US3632127

Folder: Diary Dose 1 (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	20 OCT 2020 14:20
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3632127

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 14:44:28

Generated On: 10 Jun 2021 09:08:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 20 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3632127

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:44:28

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3632127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 14:44:21

Generated On: 10 Jun 2021 09:08:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 27 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3632127

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:44:21

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3632127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 14:44:21

Generated On: 10 Jun 2021 09:08:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 3 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3632127

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:44:21

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3632127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 08 Mar 2021 14:44:28

Generated On: 10 Jun 2021 09:08:05

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 11 NOV 2020

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

Folder OID VISIT2

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Mar 2021 14:44:28

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 (<i>dd MMM yyyy</i>)	11 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	08:15 (24 HR)
Vital Signs Date and Time (derived)	11 NOV 2020 08:15
Temperature (<i>xxx.x</i>)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	80 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Mar 2021 14:44:28

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 (<i>dd MMM yyyy</i>)	11 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	10:31 (24 HR)
Vital Signs Date and Time (derived)	11 NOV 2020 10:31
Temperature (<i>xxx.x</i>)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	79 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3632127

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Mar 2021 14:44:28

Generated On: 10 Jun 2021 09:08:05

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

11 NOV 2020

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

US3632127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 08 Mar 2021 14:44:28

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) 11 NOV 2020

What was the treatment time? (00:00-23:59) 09:51 (24 HR)

Treatment Date and Time (derived) 11 NOV 2020 09:51

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

US3632127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Mar 2021 14:44:28

Generated On: 10 Jun 2021 09:08:05

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 11 NOV 2020

Collection time (*00:00-23:59*) 08:55 (24 HR)

Collection date and time (derived) 11 NOV 2020 08:55

US3632127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 08 Mar 2021 14:44:28

Generated On: 10 Jun 2021 09:08:05

Collection date (<i>dd MMM yyyy</i>)			11 NOV 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:01	11 NOV 2020 09:01
Nasopharyngeal Swab 2	No		

US3632127

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:44:28

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3632127

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 98.3 °F

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

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

PC Time Stamp 11 NOV 2020 10:29

PC Open Date & Time 11 NOV 2020 10:11

PC Close Date & Time 11 NOV 2020 12:41

US3632127

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 98.1 °F

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

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

PC Time Stamp	11 NOV 2020 19:59
PC Open Date & Time	11 NOV 2020 13:36
PC Close Date & Time	12 NOV 2020 11:59

US3632127

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	98.7 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	12 NOV 2020 15:05
PC Open Date & Time	12 NOV 2020 12:00
PC Close Date & Time	13 NOV 2020 11:59

US3632127

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

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

PC Time Stamp	13 NOV 2020 16:04
PC Open Date & Time	13 NOV 2020 12:00
PC Close Date & Time	14 NOV 2020 11:59

US3632127

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

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

PC Time Stamp	14 NOV 2020 13:50
PC Open Date & Time	14 NOV 2020 12:00
PC Close Date & Time	15 NOV 2020 11:59

US3632127

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	15 NOV 2020 14:30
PC Open Date & Time	15 NOV 2020 12:00
PC Close Date & Time	16 NOV 2020 11:59

US3632127

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.

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 type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	16 NOV 2020 14:51
PC Open Date & Time	16 NOV 2020 12:00
PC Close Date & Time	17 NOV 2020 11:59

US3632127

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	17 NOV 2020 12:05
PC Open Date & Time	17 NOV 2020 12:00
PC Close Date & Time	18 NOV 2020 11:59

US3632127

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.**
Please select one response below

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

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

- Yes
- No

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

- Yes
- No

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**
Please select one response below

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

PC Time Stamp	11 NOV 2020 10:30
PC Open Date & Time	11 NOV 2020 10:11
PC Close Date & Time	11 NOV 2020 12:41

US3632127

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

11 NOV 2020 20:00

PC Open Date & Time

11 NOV 2020 13:36

PC Close Date & Time

12 NOV 2020 11:59

US3632127

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.**

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	12 NOV 2020 15:08
PC Open Date & Time	12 NOV 2020 12:00
PC Close Date & Time	13 NOV 2020 11:59

US3632127

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.**

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	13 NOV 2020 16:04
PC Open Date & Time	13 NOV 2020 12:00
PC Close Date & Time	14 NOV 2020 11:59

US3632127

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.**

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

14 NOV 2020 13:51

PC Open Date & Time

14 NOV 2020 12:00

PC Close Date & Time

15 NOV 2020 11:59

US3632127

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.**

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	15 NOV 2020 14:31
PC Open Date & Time	15 NOV 2020 12:00
PC Close Date & Time	16 NOV 2020 11:59

US3632127

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.**

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	16 NOV 2020 14:52
PC Open Date & Time	16 NOV 2020 12:00
PC Close Date & Time	17 NOV 2020 11:59

US3632127

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.**

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	17 NOV 2020 12:06
PC Open Date & Time	17 NOV 2020 12:00
PC Close Date & Time	18 NOV 2020 11:59

US3632127

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

US3632127

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	11 NOV 2020 10:31
PC Open Date & Time	11 NOV 2020 10:11
PC Close Date & Time	11 NOV 2020 12:41

US3632127

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

US3632127

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	11 NOV 2020 20:00
PC Open Date & Time	11 NOV 2020 13:36
PC Close Date & Time	12 NOV 2020 11:59

US3632127

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

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

	Yes <input type="checkbox"/>
PC Time stamp	12 NOV 2020 15:09
PC Open Date & Time	12 NOV 2020 12:00
PC Close Date & Time	13 NOV 2020 11:59

US3632127

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

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

	Yes <input type="checkbox"/>
PC Time stamp	13 NOV 2020 16:05
PC Open Date & Time	13 NOV 2020 12:00
PC Close Date & Time	14 NOV 2020 11:59

US3632127

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

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

	Yes <input type="checkbox"/>
PC Time stamp	14 NOV 2020 13:51
PC Open Date & Time	14 NOV 2020 12:00
PC Close Date & Time	15 NOV 2020 11:59

US3632127

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

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

	Yes <input type="checkbox"/>
PC Time stamp	15 NOV 2020 14:32
PC Open Date & Time	15 NOV 2020 12:00
PC Close Date & Time	16 NOV 2020 11:59

US3632127

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

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

	Yes <input type="checkbox"/>
PC Time stamp	16 NOV 2020 14:52
PC Open Date & Time	16 NOV 2020 12:00
PC Close Date & Time	17 NOV 2020 11:59

US3632127

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

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

	Yes <input type="checkbox"/>
PC Time stamp	17 NOV 2020 12:06
PC Open Date & Time	17 NOV 2020 12:00
PC Close Date & Time	18 NOV 2020 11:59

US3632127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 14:44:21

Generated On: 10 Jun 2021 09:08:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 18 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3632127

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:44:21

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3632127

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 14:44:21

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

US3632127

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:44:21

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3632127

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 14:44:28

Generated On: 10 Jun 2021 09:08:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 3 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3632127

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:44:21

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3632127

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 08 Mar 2021 14:44:28

Generated On: 10 Jun 2021 09:08:05

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) _____

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

Folder OID VISIT3

US3632127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Mar 2021 14:44:28

Generated On: 10 Jun 2021 09:08:05

Were vital signs assessed? Yes
No

Date of assessment (*dd MMM yyyy*) _____

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

Vital Signs Date and Time (derived) _____

Temperature (*xxx.x*) _____

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (*xxx*) _____

Pulse units _____

Respiratory Rate (*xxx*) _____

Respiratory Rate units _____

Systolic Blood Pressure (*xxx*) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (*xxx*) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3632127

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Mar 2021 14:44:28

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.

US3632127

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Mar 2021 14:44:28

Generated On: 10 Jun 2021 09:08:05

Was the sample collected? Yes
No

Collection date (dd MMM yyyy) _____

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

Collection date and time (derived) _____

US3632127

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:44:28

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	True
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
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	11 DEC 2020 08:46:09
Patient Cloud Open Date & Time	10 DEC 2020 00:01

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3632127

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](#)

14 DEC 2020 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 DEC 2020 21:13:34
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 75

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3632127

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 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3632127

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	02 JAN 2021 20:28:38
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3632127

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 <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	07 JAN 2021 14:39:44
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3632127

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 JAN 2021 11:17:57
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3632127

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 22 JAN 2021 15:37:52

Patient Cloud Open Date & Time 21 JAN 2021 00:01

Patient Cloud Close Date & Time 25 JAN 2021 23:59

US3632127

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 01 FEB 2021 16:34:25

Patient Cloud Open Date & Time 28 JAN 2021 00:01

Patient Cloud Close Date & Time 01 FEB 2021 23:59

US3632127

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 05 FEB 2021 13:51:39

Patient Cloud Open Date & Time 04 FEB 2021 00:01

Patient Cloud Close Date & Time 08 FEB 2021 23:59

US3632127

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 FEB 2021 16:07:46
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3632127

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 FEB 2021 11:39:55
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3632127

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	25 FEB 2021 12:14:28
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3632127

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 MAR 2021 10:34:49
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3632127

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 MAR 2021 09:14:21
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3632127

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 MAR 2021 21:43:32
Patient Cloud Open Date & Time	18 MAR 2021 00:01
Patient Cloud Close Date & Time	22 MAR 2021 23:59

US3632127

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	26 MAR 2021 09:48:10
Patient Cloud Open Date & Time	25 MAR 2021 00:01
Patient Cloud Close Date & Time	29 MAR 2021 23:59

US3632127

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 01 APR 2021 19:58:33

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

Patient Cloud Close Date & Time 05 APR 2021 23:59

US3632127

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 08 APR 2021 16:44:25

Patient Cloud Open Date & Time 08 APR 2021 00:01

Patient Cloud Close Date & Time 12 APR 2021 23:59

US3632127

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 <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	17 APR 2021 19:12:31
Patient Cloud Open Date & Time	15 APR 2021 00:01
Patient Cloud Close Date & Time	19 APR 2021 23:59

US3632127

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

Yes

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

No

Yes

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

Date and time of submission 23 APR 2021 12:32:12

Patient Cloud Open Date & Time 22 APR 2021 00:01

Patient Cloud Close Date & Time 26 APR 2021 23:59

US3632127

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 APR 2021 17:48:13
Patient Cloud Open Date & Time	29 APR 2021 00:01
Patient Cloud Close Date & Time	03 MAY 2021 23:59

US3632127

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3632127

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3632127

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3632127

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3632127

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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	27 MAY 2021 00:01
Patient Cloud Close Date & Time	31 MAY 2021 23:59

US3632127

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3632127

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3632127

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	10 JUN 2021 00:01
Patient Cloud Close Date & Time	14 JUN 2021 23:59

US3632127

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 Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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	17 JUN 2021 00:01
Patient Cloud Close Date & Time	21 JUN 2021 23:59

US3632127

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°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

US3632127

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 2021 00:01
Patient Cloud Close Date & Time	28 JUN 2021 23:59

US3632127

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 Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3632127

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

US3632127

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](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3632127

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
Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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	15 JUL 2021 00:01
Patient Cloud Close Date & Time	19 JUL 2021 23:59

US3632127

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 Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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	22 JUL 2021 00:01
Patient Cloud Close Date & Time	26 JUL 2021 23:59

US3632127

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
Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3632127

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](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3632127

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
Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3632127

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3632127

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

US3632127

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](#) 12 AUG 2021 00:01

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

US3632127

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
Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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	19 AUG 2021 00:01
Patient Cloud Close Date & Time	23 AUG 2021 23:59

US3632127

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
Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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	26 AUG 2021 00:01
Patient Cloud Close Date & Time	30 AUG 2021 23:59

US3632127

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°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

US3632127

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](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3632127

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3632127

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	09 SEP 2021 00:01
Patient Cloud Close Date & Time	13 SEP 2021 23:59

US3632127

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3632127

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](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3632127

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3632127

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	23 SEP 2021 00:01
Patient Cloud Close Date & Time	27 SEP 2021 23:59

US3632127

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 Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3632127

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°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

US3632127

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](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3632127

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°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

US3632127

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 2021 00:01

[Patient Cloud Close Date & Time](#) 18 OCT 2021 23:59

US3632127

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°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

US3632127

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](#) 21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#) 25 OCT 2021 23:59

US3632127

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
Yes

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

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

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

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

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

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

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

US3632127

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	28 OCT 2021 00:01
Patient Cloud Close Date & Time	01 NOV 2021 23:59

US3632127

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
Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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 NOV 2021 00:01
Patient Cloud Close Date & Time	08 NOV 2021 23:59

US3632127

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°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

US3632127

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](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3632127

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
Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3632127

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 Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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	25 NOV 2021 00:01
Patient Cloud Close Date & Time	29 NOV 2021 23:59

US3632127

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 Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3632127

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
Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3632127

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
Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3632127

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
Yes

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

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

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

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

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

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

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

US3632127

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](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3632127

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 Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3632127

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
Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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	06 JAN 2022 00:01
Patient Cloud Close Date & Time	10 JAN 2022 23:59

US3632127

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
Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3632127

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
Yes

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

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

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

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

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

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

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

US3632127

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3632127

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°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

US3632127

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](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3632127

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
Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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](#) 03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#) 07 FEB 2022 23:59

US3632127

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 Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3632127

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
Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3632127

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°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

US3632127

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 FEB 2022 00:01

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

US3632127

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°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

US3632127

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](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3632127

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
Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3632127

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](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3632127

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°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

US3632127

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](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3632127

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 Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3632127

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°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

US3632127

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](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3632127

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
Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3632127

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°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

US3632127

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3632127

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°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

US3632127

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](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3632127

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

US3632127

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	28 APR 2022 00:01
Patient Cloud Close Date & Time	02 MAY 2022 23:59

US3632127

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

US3632127

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3632127

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
Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3632127

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°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

US3632127

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](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3632127

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

US3632127

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](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3632127

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
Yes

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

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

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

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

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

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

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

US3632127

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](#) 02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#) 06 JUN 2022 23:59

US3632127

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°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

US3632127

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](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3632127

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
Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3632127

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3632127

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](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3632127

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
Yes

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

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

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

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

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

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

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

US3632127

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3632127

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
Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3632127

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](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3632127

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
Yes

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

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

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

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

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

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

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

US3632127

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3632127

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
Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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	21 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

US3632127

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
Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3632127

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](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3632127

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
Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3632127

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
Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3632127

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°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

US3632127

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3632127

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
Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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](#) 25 AUG 2022 00:01

[Patient Cloud Close Date & Time](#) 29 AUG 2022 23:59

US3632127

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 Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3632127

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
Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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	08 SEP 2022 00:01
Patient Cloud Close Date & Time	12 SEP 2022 23:59

US3632127

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°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

US3632127

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](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3632127

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
Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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	22 SEP 2022 00:01
Patient Cloud Close Date & Time	26 SEP 2022 23:59

US3632127

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
Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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	29 SEP 2022 00:01
Patient Cloud Close Date & Time	03 OCT 2022 23:59

US3632127

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
Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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](#) 06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#) 10 OCT 2022 23:59

US3632127

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 Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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	13 OCT 2022 00:01
Patient Cloud Close Date & Time	17 OCT 2022 23:59

US3632127

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
Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3632127

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 OCT 2022 00:01
Patient Cloud Close Date & Time	24 OCT 2022 23:59

US3632127

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
Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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	27 OCT 2022 00:01
Patient Cloud Close Date & Time	31 OCT 2022 23:59

US3632127

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°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

US3632127

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](#)

03 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3632127

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

US3632127

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](#) 10 NOV 2022 00:01

[Patient Cloud Close Date & Time](#) 14 NOV 2022 23:59

US3632127

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
Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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](#)

17 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2022 23:59

US3632127

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

US3632127

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 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2022 23:59

US3632127

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 Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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](#) 01 DEC 2022 00:01

[Patient Cloud Close Date & Time](#) 05 DEC 2022 23:59

US3632127

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°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

US3632127

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](#)

08 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2022 23:59

US3632127

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
Yes

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3632127

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	15 DEC 2022 00:01
Patient Cloud Close Date & Time	19 DEC 2022 23:59

US3632127

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		05 MAR 2021 10:35:14

US3632127

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 14:44:28

Generated On: 10 Jun 2021 09:08:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 6 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3632127

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 14:44:28

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3632127

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 01:17:45

Generated On: 10 Jun 2021 09:08:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 12 FEB 2021

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

Comments COMPLETED WHILE
PARTICIPANT WAS HERE FOR
If Contact Not Made, please provide Comments OL-2.

US3632127

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 01:17:45

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3632127

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 01:17:45

Generated On: 10 Jun 2021 09:08:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 11 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3632127

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 01:17:45

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3632127

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 01:37:15

Generated On: 10 Jun 2021 09:08:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 9 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3632127

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 01:37:15

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3632127

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3632127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	_____
Time of assessment (<i>00:00-23:59</i>)	_____
Vital Signs Date and Time (derived)	_____
Temperature (<i>xxx.x</i>)	_____
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	_____
Pulse units	_____
Respiratory Rate (<i>xxx</i>)	_____
Respiratory Rate units	_____
Systolic Blood Pressure (<i>xxx</i>)	_____
Systolic Blood Pressure units	_____
Diastolic Blood Pressure (<i>xxx</i>)	_____
Diastolic Blood Pressure units	_____
Height (derived)	_____
Weight (derived)	_____

US3632127

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

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.

US3632127

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

Was the sample collected? Yes
No

Collection date (*dd MMM yyyy*) _____

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

Collection date and time (derived) _____

US3632127

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 05 Apr 2021 01:17:35

Generated On: 10 Jun 2021 09:08:05

Date of Contact	11 DEC 2020
Time of Contact	09:00
Date and Time of Contact (derived)	11 DEC 2020 09:00
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input checked="" type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 01:17:36

Generated On: 10 Jun 2021 09:08:05

Symptom Day

Day 1	<input checked="" 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 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"/>

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 01:17:36

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	6 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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EAB) (1725)

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 01:17:36

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"/>

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 01:17:36

Generated On: 10 Jun 2021 09:08:05

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 01:17:36

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"/>

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 01:17:36

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	7 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 11 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 01:17:36

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"/>

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 01:17:36

Generated On: 10 Jun 2021 09:08:05

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 01:17:36

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"/>

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 01:17:36

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 8 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"/>

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 01:17:36

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"/>

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 01:17:36

Generated On: 10 Jun 2021 09:08:05

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 01:17:36

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"/>

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 01:17:36

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	9 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
EAB) (1725)

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 01:17:36

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"/>

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 01:17:36

Generated On: 10 Jun 2021 09:08:05

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 01:17:36

Generated On: 10 Jun 2021 09:08:05

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 01:17:36

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	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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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 01:17:36

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"/>

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 01:17:36

Generated On: 10 Jun 2021 09:08:05

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 01:17:36

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"/>

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 01:17:36

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 99 %

O2 Saturation Units %

Temperature 98.7 F

Chills

None

Mild

Moderate

Severe

Not Done

Cough

None

Mild

Moderate

Severe

Not Done

Shortness of Breath

None

Mild

Moderate

Severe

Not Done

Difficulty Breathing

None

Mild

Moderate

Severe

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EAB) (1725)

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 01:17:36

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 type="radio"/>
	Mild <input checked="" 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"/>

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 01:17:36

Generated On: 10 Jun 2021 09:08:05

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 01:17:36

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"/>

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 01:17:36

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	12 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	96 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.1 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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EAB) (1725)

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 01:17:36

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 type="radio"/>
	Mild <input checked="" 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"/>

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 01:17:36

Generated On: 10 Jun 2021 09:08:05

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 01:17:36

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"/>

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 01:17:36

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	13 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.9 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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EAB) (1725)

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 01:17:36

Generated On: 10 Jun 2021 09:08:05

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 01:17:36

Generated On: 10 Jun 2021 09:08:05

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 05 Apr 2021 01:17:36

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 type="checkbox"/>
Day 9	<input checked="" 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"/>

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 05 Apr 2021 01:17:36

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	14 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	96 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.9 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 05 Apr 2021 01:17:36

Generated On: 10 Jun 2021 09:08:05

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 05 Apr 2021 01:17:36

Generated On: 10 Jun 2021 09:08:05

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 05 Apr 2021 01:17:35

Generated On: 10 Jun 2021 09:08:05

Date of Visit 11 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 11 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

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 22 Apr 2021 15:42:59

Generated On: 10 Jun 2021 09:08:05

Date of Contact	18 NOV 2020
Time of Contact	08:00
Date and Time of Contact (derived)	18 NOV 2020 08:00
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input checked="" type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 01:17:35

Generated On: 10 Jun 2021 09:08:05

Symptom Day

Day 1	<input checked="" 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 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 18 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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 17 NOV 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
EAB) (1725)

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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"/>

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 01:17:35

Generated On: 10 Jun 2021 09:08:05

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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"/>

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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	18 NOV 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

EAB) (1725)

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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"/>

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 01:17:35

Generated On: 10 Jun 2021 09:08:05

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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"/>

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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 19 NOV 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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"/>

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 01:17:35

Generated On: 10 Jun 2021 09:08:05

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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"/>

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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	20 NOV 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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"/>

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 01:17:35

Generated On: 10 Jun 2021 09:08:05

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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"/>

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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	21 NOV 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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EAB) (1725)

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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"/>

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 01:17:35

Generated On: 10 Jun 2021 09:08:05

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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"/>

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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 22 NOV 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 01:17:35

Generated On: 10 Jun 2021 09:08:05

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 01:17:35

Generated On: 10 Jun 2021 09:08:05

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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"/>

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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	23 NOV 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 01:17:35

Generated On: 10 Jun 2021 09:08:05

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 01:17:35

Generated On: 10 Jun 2021 09:08:05

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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"/>

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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	24 NOV 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 01:17:35

Generated On: 10 Jun 2021 09:08:05

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 01:17:35

Generated On: 10 Jun 2021 09:08:05

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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 type="checkbox"/>
Day 9	<input checked="" 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 18 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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 25 NOV 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 05 Apr 2021 01:17:35

Generated On: 10 Jun 2021 09:08:05

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 05 Apr 2021 01:17:35

Generated On: 10 Jun 2021 09:08:05

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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 type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" 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 18 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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 26 NOV 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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"/>

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 05 Apr 2021 01:17:35

Generated On: 10 Jun 2021 09:08:05

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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 type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" 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 18 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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 27 NOV 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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"/>

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 05 Apr 2021 01:17:35

Generated On: 10 Jun 2021 09:08:05

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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 type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input checked="" 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"/>

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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 28 NOV 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 05 Apr 2021 01:17:35

Generated On: 10 Jun 2021 09:08:05

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 05 Apr 2021 01:17:35

Generated On: 10 Jun 2021 09:08:05

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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 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 checked="" 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"/>

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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	29 NOV 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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EAB) (1725)

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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"/>

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 05 Apr 2021 01:17:35

Generated On: 10 Jun 2021 09:08:05

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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 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 checked="" 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"/>

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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	30 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97 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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EAB) (1725)

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 05 Apr 2021 01:17:35

Generated On: 10 Jun 2021 09:08:05

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 05 Apr 2021 01:17:35

Generated On: 10 Jun 2021 09:08:05

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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 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 checked="" 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"/>

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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	1 DEC 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	96 %
---------------	------

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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EAB) (1725)

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 05 Apr 2021 01:17:35

Generated On: 10 Jun 2021 09:08:05

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 05 Apr 2021 01:17:35

Generated On: 10 Jun 2021 09:08:05

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 05 Apr 2021 01:17:35

Generated On: 10 Jun 2021 09:08:05

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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	2 DEC 2020
------	------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<hr/>
---------------	-------

O2 Saturation Units	<hr/>
---------------------	-------

Temperature	<hr/>
-------------	-------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 05 Apr 2021 01:17:35

Generated On: 10 Jun 2021 09:08:05

	Not Done <input type="checkbox"/>
Fatigue	None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Not Done <input type="checkbox"/>
Muscle Aches (Myalgia)	None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Not Done <input type="checkbox"/>
Body Aches	None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Not Done <input type="checkbox"/>
Headache	None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Not Done <input type="checkbox"/>
New Loss of Taste	None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Not Done <input type="checkbox"/>
New Loss of Smell	None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Not Done <input type="checkbox"/>

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 05 Apr 2021 01:17:35

Generated On: 10 Jun 2021 09:08:05

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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 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 checked="" 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 18 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 05 Apr 2021 01:17:35

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 3 DEC 2020

Assessment Not Done False

O2 Saturation 97 %

O2 Saturation Units %

Temperature 98.2 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 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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EAB) (1725)

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 05 Apr 2021 01:17:35

Generated On: 10 Jun 2021 09:08:05

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 05 Apr 2021 01:17:35

Generated On: 10 Jun 2021 09:08:05

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 05 Apr 2021 01:17:35

Generated On: 10 Jun 2021 09:08:05

Date of Visit 30 NOV 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 30 NOV 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

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 05 Apr 2021 01:17:35

Generated On: 10 Jun 2021 09:08:05

[Generate Next COVID-19 Assessment](#)

Yes

No

US3632127

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 05 Apr 2021 01:17:36

Generated On: 10 Jun 2021 09:08:05

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	2 DEC 2020
Day 5	NA (COVID-19 Negative)	
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)	

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Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 05 Apr 2021 01:17:36

Generated On: 10 Jun 2021 09:08:05

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	13 DEC 2020
Day 5	NA (COVID-19 Negative)	
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)	

US3632127

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 01:17:36

Generated On: 10 Jun 2021 09:08:05

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 30 NOV 2020

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

Folder OID SICKD1

US3632127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 01:17:36

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>)	30 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	08:16 (24 HR)
Vital Signs Date and Time (derived)	30 NOV 2020 08:16
Height (<i>xxx.x</i>)	64.5 in
Weight (<i>xxx.x</i>)	245.4 lb
Temperature (<i>xxx.x</i>)	97 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	75 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	101 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3632127

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 01:17:36

Generated On: 10 Jun 2021 09:08:05

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

30 NOV 2020

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

US3632127

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 05 Apr 2021 01:17:36

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

30 NOV 2020

US3632127

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 01:17:36

Generated On: 10 Jun 2021 09:08:05

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 11 DEC 2020

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

Folder OID SICKD1

US3632127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 01:17:36

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>)	11 DEC 2020
Time of assessment (<i>00:00-23:59</i>)	11:10 (24 HR)
Vital Signs Date and Time (derived)	11 DEC 2020 11:10
Height (<i>xxx.x</i>)	64.5 in
Weight (<i>xxx.x</i>)	247.6 lb
Temperature (<i>xxx.x</i>)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	78 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	89 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3632127

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 01:17:36

Generated On: 10 Jun 2021 09:08:05

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

11 DEC 2020

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

US3632127

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 05 Apr 2021 01:17:36

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

11 DEC 2020

US3632127

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 01:17:35

Generated On: 10 Jun 2021 09:08:05

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) _____

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

Folder OID SICKD28

US3632127

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	_____
Time of assessment (<i>00:00-23:59</i>)	_____
Vital Signs Date and Time (derived)	_____
Temperature (<i>xxx.x</i>)	_____
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	_____
Pulse units	_____
Respiratory Rate (<i>xxx</i>)	_____
Respiratory Rate units	_____
Systolic Blood Pressure (<i>xxx</i>)	_____
Systolic Blood Pressure units	_____
Diastolic Blood Pressure (<i>xxx</i>)	_____
Diastolic Blood Pressure units	_____
Height (derived)	_____
Weight (derived)	_____

US3632127

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

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.

US3632127

Folder: Convalescence Visit Day 28 (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?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection _____

US3632127

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3632127

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	_____
Time of assessment (<i>00:00-23:59</i>)	_____
Vital Signs Date and Time (derived)	_____
Temperature (<i>xxx.x</i>)	_____
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	_____
Pulse units	_____
Respiratory Rate (<i>xxx</i>)	_____
Respiratory Rate units	_____
Systolic Blood Pressure (<i>xxx</i>)	_____
Systolic Blood Pressure units	_____
Diastolic Blood Pressure (<i>xxx</i>)	_____
Diastolic Blood Pressure units	_____
Height (derived)	_____
Weight (derived)	_____

US3632127

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

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.

US3632127

Folder: Convalescence Visit Day 28 (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?

Yes

No

NA (COVID-19 Negative)

Date of Collection _____

US3632127

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

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 01:17:45

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)	15 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

US3632127

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 01:37:15

Generated On: 10 Jun 2021 09:08:05

Date of updated informed consent (<i>dd MMM yyyy</i>)	15 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	15 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3632127

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Apr 2021 01:17:45

Generated On: 10 Jun 2021 09:08:05

Height	65 in
Weight	247.4 lb
BMI (xxx.x)	41.25560

US3632127

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 01:17:45

Generated On: 10 Jun 2021 09:08:05

Height	65 in
Weight	247.4 lb
BMI (xxx.x)	41.25560
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)	15 JAN 2021
Time of assessment (00:00-23:59)	09:45 (24 HR)
Vital Signs Date and Time (derived)	15 JAN 2021 09:45
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3632127

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 01:17:45

Generated On: 10 Jun 2021 09:08:05

Height	65 in
Weight	247.4 lb
BMI (xxx.x)	41.25560
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)	15 JAN 2021
Time of assessment (00:00-23:59)	11:56 (24 HR)
Vital Signs Date and Time (derived)	15 JAN 2021 11:56
Temperature (xxx.x)	96.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3632127

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

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 01:17:45

Generated On: 10 Jun 2021 09:08:05

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

15 JAN 2021

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

US3632127

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

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 01:17:45

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 15 JAN 2021

What was the treatment time? (00:00-23:59) 11:25 (24 HR)

Treatment Date and Time (derived) 15 JAN 2021 11:25

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

US3632127

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 01:17:45

Generated On: 10 Jun 2021 09:08:05

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 15 JAN 2021

Collection time (*00:00-23:59*) 10:15 (24 HR)

Collection date and time (derived) 15 JAN 2021 10:15

US3632127

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Apr 2021 01:17:45

Generated On: 10 Jun 2021 09:08:05

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 15 JAN 2021

Collection time (*00:00 - 23:59*) 10:12

Collection Date and Time (derived) 15 JAN 2021 10:12

US3632127

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

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 01:17:45

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3632127

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 01:17:45

Generated On: 10 Jun 2021 09:08:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 22 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3632127

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 01:17:45

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3632127

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:08:05

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 12 FEB 2021

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

Folder OID OLD29

US3632127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 01:17:44

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 (<i>dd MMM yyyy</i>)	12 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	10:24 (24 HR)
Vital Signs Date and Time (derived)	12 FEB 2021 10:24
Temperature (<i>xxx.x</i>)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	83 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3632127

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 01:17:44

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 (<i>dd MMM yyyy</i>)	12 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	12:11 (24 HR)
Vital Signs Date and Time (derived)	12 FEB 2021 12:11
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	79 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3632127

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 01:17:36

Generated On: 10 Jun 2021 09:08:05

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

12 FEB 2021

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

US3632127

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 01:17:36

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 12 FEB 2021

What was the treatment time? (00:00-23:59) 11:40 (24 HR)

Treatment Date and Time (derived) 12 FEB 2021 11:40

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

US3632127

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 01:17:36

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3632127

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 01:17:45

Generated On: 10 Jun 2021 09:08:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 19 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3632127

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 01:17:45

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3632127

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 01:17:44

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)	12 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	OLD57

US3632127

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:08:05

Were vital signs assessed? Yes
No

Date of assessment (*dd MMM yyyy*) _____

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

Vital Signs Date and Time (derived) _____

Temperature (*xxx.x*) _____

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (*xxx*) _____

Pulse units _____

Respiratory Rate (*xxx*) _____

Respiratory Rate units _____

Systolic Blood Pressure (*xxx*) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (*xxx*) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3632127

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 01:17:44

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.

US3632127

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:08:05

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 12 MAR 2021

Collection time (*00:00-23:59*) 15:03 (24 HR)

Collection date and time (derived) 12 MAR 2021 15:03

US3632127

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 12:27:39

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.

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Mar 2021 12:27:38

Generated On: 10 Jun 2021 09:08:05

AEID USA-US120-2020-MRNA-1273-P30
1000004

Adverse event SEXUAL ASSAULT

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) 07 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 7 NOV 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 True

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

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Mar 2021 12:27:38

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	True
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	PARTICIPANT WAS A VICTIM OF SEXUAL ASSAULT.
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)	

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Mar 2021 12:27:38

Generated On: 10 Jun 2021 09:08:05

AEID

Adverse event FRACTURED, 4TH, RIGHT TOE.

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) 7 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes No

If not Ongoing, end date (dd MMM yyyy) 15 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

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Mar 2021 12:27:38

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> 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	FRACTURE OCCURED DURING THE SEXUAL ASSAULT
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)	

US3632127

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Mar 2021 12:27:38

Generated On: 10 Jun 2021 09:08:05

AEID	
Adverse event	CRAMPING
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)	6 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	6 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Mar 2021 12:27:38

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
 Related
 Not Applicable

Relationship to Study Procedure Not Related
 Related
 Not Applicable

Action taken with investigational product None
 Dose Delayed
 Investigational Product
 Withdrawn
 Not Applicable

Other action taken (check all that apply)

None True

Concomitant Medication False

Concomitant Procedure False

Outcome Fatal
 Not Recovered/Not Resolved
 Recovered/Resolved
 Recovered/Resolved with Sequelae
 Recovering/Resolving
 Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative

US3632127

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Mar 2021 12:27:38

Generated On: 10 Jun 2021 09:08:05

PARTICIPANT EXPERIENCED SEVERE CRAMPING ON UPPER THIGHS AND LOWER ABDOMEN AND CALLED EMS DUE TO CONCERN FOR CARDIAC EVENT. UPON ARRIVAL, PARTICIPANT DID NOT CONSENT TO A VISIT TO THE ER, BUT WAS TREATED BY EMTS AT SITE. AFTER RECEIVING AN IV, PARTICIPANT'S CRAMPING RESOLVED.

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)	

US3632127

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 15 Mar 2021 12:27:38

Generated On: 10 Jun 2021 09:08:05

AEID

Adverse event INTERMITTENT COUGH

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) 13 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

US3632127

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 15 Mar 2021 12:27:38

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input 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)	_____

US3632127

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 15 Mar 2021 12:27:38

Generated On: 10 Jun 2021 09:08:05

AEID

Adverse event

URINARY 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)

19 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

03 MAR 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 (5)

Data signed: (b) (4) 15 Mar 2021 12:27:38

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)	_____

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Apr 2021 01:17:35

Generated On: 10 Jun 2021 09:08:05

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

Yes

No

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

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 15:42:59

Generated On: 10 Jun 2021 09:08:05

Name of Medication LISINOPRIL HCTZ

Prophylaxis Yes
No

Indication HYPERTENSION

Dose per administration 10/12.5

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 15:42:59

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*) 01 UNK 2010

Start date completely unknown False

Ongoing? Yes
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 15:42:59

Generated On: 10 Jun 2021 09:08:05

Name of Medication FISH OILS

Prophylaxis Yes
No

Indication HYPERTENSION

Dose per administration 360

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) 22 Apr 2021 15:42:59

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*) 01 UNK 2010

Start date completely unknown False

Ongoing? Yes
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 15:42:59

Generated On: 10 Jun 2021 09:08:05

Name of Medication ASPIRIN

Prophylaxis Yes
No

Indication HEART ATTACK PREVENTION

Dose per administration 81

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 15:42:59

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*) 01 UNK 2010

Start date completely unknown False

Ongoing? Yes
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 15:42:59

Generated On: 10 Jun 2021 09:08:05

Name of Medication TURMERIC

Prophylaxis Yes
No

Indication OSTEOARTHRITIS

Dose per administration 538

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 15:42:59

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*) 01 UNK 2010

Start date completely unknown False

Ongoing? Yes
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 15:42:59

Generated On: 10 Jun 2021 09:08:05

Name of Medication NAPROXEN ORAL SUSPENSION

Prophylaxis Yes
No

Indication OSTEOARTHRITIS &
RHEUMATOID ARTHRITIS

Dose per administration 125

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 (5)

Data signed: (b) (4) 22 Apr 2021 15:42:59

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) 01 UNK 2005

Start date completely unknown False

Ongoing? Yes
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 15:42:59

Generated On: 10 Jun 2021 09:08:05

Name of Medication POWER C GUMMIES

Prophylaxis Yes
No

Indication GENERAL HEALTH

Dose per administration 2

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify GUMMIES

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) 22 Apr 2021 15:42:59

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*) 01 FEB 2020

Start date completely unknown False

Ongoing? Yes
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 15:42:59

Generated On: 10 Jun 2021 09:08:05

Name of Medication CRANBERRY

Prophylaxis Yes
No

Indication GENERAL HEALTH

Dose per administration 4200

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 15:42:59

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*) 01 UNK 2005

Start date completely unknown False

Ongoing? Yes
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 15:42:59

Generated On: 10 Jun 2021 09:08:05

Name of Medication POTASSIUM

Prophylaxis Yes
No

Indication HYPERTENSION

Dose per administration 10

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify MEQ

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 15:42:59

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*) 01 APR 2020

Start date completely unknown False

Ongoing? Yes
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 15:42:59

Generated On: 10 Jun 2021 09:08:05

Name of Medication MAGNESIUM

Prophylaxis Yes
No

Indication CONSTIPATION

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 15:42:59

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*) 01 APR 2020

Start date completely unknown False

Ongoing? Yes
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Apr 2021 15:42:59

Generated On: 10 Jun 2021 09:08:05

Name of Medication PROBIOTIC

Prophylaxis Yes
No

Indication GENERAL HEALTH

Dose per administration 2

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Apr 2021 15:42:59

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*) 01 UNK 2015

Start date completely unknown False

Ongoing? Yes
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 22 Apr 2021 15:42:59

Generated On: 10 Jun 2021 09:08:05

Name of Medication APPLE CIDER VINEGAR

Prophylaxis Yes
No

Indication GENERAL HEALTH

Dose per administration 480

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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EAB) (1725)

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US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 22 Apr 2021 15:42:59

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*) 01 UNK 2018

Start date completely unknown False

Ongoing? Yes
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 22 Apr 2021 15:42:59

Generated On: 10 Jun 2021 09:08:05

Name of Medication ELDERBERRY

Prophylaxis Yes
No

Indication GENERAL HEALTH

Dose per administration 1250

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 22 Apr 2021 15:42:59

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*) 01 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 22 Apr 2021 15:42:59

Generated On: 10 Jun 2021 09:08:05

Name of Medication NAPROXEN

Prophylaxis Yes
No

Indication OSTEOARTHRITIS/RHEUMATOI
D ARTHRITIS

Dose per administration 500

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 22 Apr 2021 15:42:59

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) 13 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 13 OCT 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 22 Apr 2021 15:42:59

Generated On: 10 Jun 2021 09:08:05

Name of Medication PRAVASTATIN

Prophylaxis Yes
No

Indication SLIGHTLY ELEVATED
CHOLESTEROL

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 22 Apr 2021 15:42:59

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)	19 OCT 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"/>

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 22 Apr 2021 15:42:59

Generated On: 10 Jun 2021 09:08:05

Name of Medication VITAMIN D3

Prophylaxis Yes
No

Indication TO HELP WITH BONE HEALTH

Dose per administration 5000

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 22 Apr 2021 15:42:59

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*) 01 MAY 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) UN UNK 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 22 Apr 2021 15:42:59

Generated On: 10 Jun 2021 09:08:05

Name of Medication VOLTAREN GEL (DICLOFENAC SODIUM 1% GEL)

Prophylaxis Yes
No

Indication RHEUMATOID ARTHRITIS

Dose per administration 2

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 22 Apr 2021 15:42:59

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)	01 UNK 2019
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

Separate Dosage Number (derived)	_____
Interval Dosage Unit Number (derived)	_____
Interval Dosage Definition (derived)	802 <input type="checkbox"/>
	803 <input type="checkbox"/>
	804 <input type="checkbox"/>

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 22 Apr 2021 15:42:59

Generated On: 10 Jun 2021 09:08:05

Name of Medication CEFTRIAXONE

Prophylaxis Yes
No

Indication SEXUAL ASSAULT (AE)-
PRESUMPTIVE TREATMENT OF
STI'S

Dose per administration 250

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 22 Apr 2021 15:42:59

Generated On: 10 Jun 2021 09:08:05

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

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 07 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 07 NOV 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 22 Apr 2021 15:42:59

Generated On: 10 Jun 2021 09:08:05

Name of Medication ZITHROMAX

Prophylaxis Yes
No

Indication SEXUAL ASSAULT (AE)-
PRESUMPTIVE TREATMENT OF
STI'S

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 22 Apr 2021 15:42:59

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) 07 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 07 NOV 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 22 Apr 2021 15:42:59

Generated On: 10 Jun 2021 09:08:05

Name of Medication FLAGYL

Prophylaxis Yes
No

Indication SEXUAL ASSAULT (AE)-
PRESUMPTIVE TREATMENT OF
STI'S

Dose per administration 2

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 22 Apr 2021 15:42:59

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) 07 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 07 NOV 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 22 Apr 2021 15:42:59

Generated On: 10 Jun 2021 09:08:05

Name of Medication TIVICAY (DOLUTEGRAVIR)

Prophylaxis Yes
No

Indication SEXUAL ASSAULT (AE #1)

Dose per administration 50

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 22 Apr 2021 15:42:59

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*) 12 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 20 NOV 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 22 Apr 2021 15:42:59

Generated On: 10 Jun 2021 09:08:05

Name of Medication EMTRICITABINE AND
TENOFIVIR DISOPROXIL
FUMARATE

Prophylaxis Yes
No

Indication SEXUAL ASSAULT

Dose per administration 200/300

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 22 Apr 2021 15:42:59

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)	12 NOV 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

If not Ongoing, End date (dd MMM yyyy)	20 NOV 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"/>

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 22 Apr 2021 15:42:59

Generated On: 10 Jun 2021 09:08:05

Name of Medication NAPROXEN

Prophylaxis Yes
No

Indication FRACTURED TOE (AE)

Dose per administration 500

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 22 Apr 2021 15:42:59

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*) 7 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 15 DEC 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 22 Apr 2021 15:42:59

Generated On: 10 Jun 2021 09:08:05

Name of Medication TYLENOL

Prophylaxis Yes
No

Indication ARM SORENESS AFTER OL
VACCINATION

Dose per administration 1,000

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 22 Apr 2021 15:42:59

Generated On: 10 Jun 2021 09:08:05

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

If route of administration is Other, specify _____

Start date (dd MMM yyyy)	15 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)	15 JAN 2021
--	-------------

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"/>

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 22 Apr 2021 15:42:59

Generated On: 10 Jun 2021 09:08:05

Name of Medication NAPROXEN

Prophylaxis Yes
No

Indication PAIN IN ARM AFTER OL
VACCINATION

Dose per administration 550

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 22 Apr 2021 15:42:59

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) 16 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 16 JAN 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 22 Apr 2021 15:42:59

Generated On: 10 Jun 2021 09:08:05

Name of Medication HYDROCODONE

Prophylaxis Yes
No

Indication LEFT ARM PAIN AFTER OL
VACCINE

Dose per administration 7.5

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

543 of 3457

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 22 Apr 2021 15:42:59

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) 17 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 17 JAN 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 22 Apr 2021 15:42:59

Generated On: 10 Jun 2021 09:08:05

Name of Medication VITAMIN D3

Prophylaxis Yes
No

Indication GENERAL BONE HEALTH

Dose per administration 25

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

545 of 3457

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 22 Apr 2021 15:42:59

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 2021

Start date completely unknown False

Ongoing? Yes
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 22 Apr 2021 15:42:59

Generated On: 10 Jun 2021 09:08:05

Name of Medication FLUCONAZOLE

Prophylaxis Yes
No

Indication URINARY TRACT INFECTION

Dose per administration 150

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

ONCE DAILY FOR 2 DAYS

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

547 of 3457

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 22 Apr 2021 15:42:59

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*) 25 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 26 FEB 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 22 Apr 2021 15:42:59

Generated On: 10 Jun 2021 09:08:05

Name of Medication NITROFURANTOIN

Prophylaxis Yes
No

Indication URINARY 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 TWICE DAILY FOR 5 DAYS

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

549 of 3457

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 22 Apr 2021 15:42:59

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*) 25 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 01 MAR 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802

803

804

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 22 Apr 2021 15:42:59

Generated On: 10 Jun 2021 09:08:05

Name of Medication PHENTERMINE

Prophylaxis Yes
No

Indication SEVERE OBESITY

Dose per administration 37.5

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 22 Apr 2021 15:42:59

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*) 05 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 13 FEB 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3632127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Apr 2021 01:17:35

Generated On: 10 Jun 2021 09:08:05

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3632127

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

US3632127

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

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 05 Apr 2021 01:17:45

Generated On: 10 Jun 2021 09:08:05

SAEID	USA-US120-2020-MRNA-1273-P30 1000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 05 Apr 2021 01:17:45

Generated On: 10 Jun 2021 09:08:05

SAEID	USA-US120-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	11/NOV/2020 20:57
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	<input checked="" type="checkbox"/> True

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 05 Apr 2021 01:17:45

Generated On: 10 Jun 2021 09:08:05

SAEID	USA-US120-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	16/NOV/2020 09:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	<input checked="" type="checkbox"/> True

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 05 Apr 2021 01:17:45

Generated On: 10 Jun 2021 09:08:05

SAEID	USA-US120-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	20/NOV/2020 10:42
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

US3632127 (Prod: Grady Health System)

US3632127

Form: Participant Creation

Generated On: 10 Jun 2021 09:08:05

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:02:02
User entered 'US3632127'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Oct 2020 15:33:31

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:25:56
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:57:47

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:25:56
User entered '13 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Oct 2020 15:33:33

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:25:56
User entered 'Clinic (Clinic)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:57:47

US3632127

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 00:05:10
User entered 'SCRN'	System	13 Oct 2020 17:57:47

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:26:11
User entered (b) (6) 1963'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Oct 2020 15:33:34

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:26:11
User entered '57'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:15

US3632127

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 00:05:10
User entered 'YEARS'	System	13 Oct 2020 17:58:15

US3632127

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 00:05:10
User entered '57'	System	13 Oct 2020 17:58:31

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:26:11
User entered 'Female (F)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:15

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:26:11
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:15

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:26:11
User entered '0'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:15

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:26:11
User entered '1'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:15

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:26:11
User entered '0'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:15

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:26:11
User entered '0'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:15

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:26:11
User entered '0'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:15

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:26:11
User entered '0'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:15

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:26:11
User entered empty.	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:15

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:26:11
User entered '0'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:15

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:26:11
User entered '0'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:15

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:26:26
User entered '13 Oct 2020'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:31

US3632127

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 00:05:10
User entered 'Oct 2020'	System	13 Oct 2020 17:58:31

US3632127

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 00:05:10
User entered '2020'	System	13 Oct 2020 17:58:31

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:26:26
User entered 'Amendment 4 (4)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:31

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:26:26
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:31

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:26:26
User entered empty.	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:31

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:26:26
User entered empty.	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:31

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:26:26
User entered 'No (N)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:31

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:26:26
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	13 Oct 2020 15:33:33

US3632127

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 00:05:10
User entered '1'	System	13 Oct 2020 17:58:39

US3632127

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 00:05:10
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:44:39
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
User entered 'Yes (Y)'	(b) (4) Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:39

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:37:07
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:48

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:39:46
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Anaphylactic and anaphylactoid responses, PT: Anaphylactic reaction, LLT: Anaphylactic reaction to drug - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Jan 2021 15:45:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Jan 2021 15:45:50
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 05:03:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 05:03:21
Data point term sent to Coder	System	13 Oct 2020 20:48:27
User entered 'Geodon Allergy (anaphylaxis)'	(b) (4), (b) (6)	13 Oct 2020 20:47:28

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:39:46
User entered '1 UNK 1993'	(b) (4), (b) (6)	13 Oct 2020 20:47:28

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:39:46
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:47:28

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:39:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:47:28

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:39:46
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:47:28

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:39:46
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:47:28

US3632127

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 00:05:10
User entered 'Jan 1993'	System	13 Oct 2020 20:47:28

US3632127

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 00:05:10
User entered '1993'	System	13 Oct 2020 20:47:28

US3632127

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 00:05:10
User entered empty.	System	13 Oct 2020 20:47:28

US3632127

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 00:05:10
User entered empty.	System	13 Oct 2020 20:47:28

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:39:49
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:49:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:49:23
Data point term sent to Coder	System	13 Oct 2020 20:48:27
User entered 'Hypertension'	(b) (4), (b) (6)	13 Oct 2020 20:47:39

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:39:49
User entered '1 UNK 2010'	(b) (4), (b) (6)	13 Oct 2020 20:47:39

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:39:49
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:47:39

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:39:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:47:39

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:39:49
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:47:39

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:39:49
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:47:39

US3632127

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 00:05:10
User entered 'Jan 2010'	System	13 Oct 2020 20:47:39

US3632127

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 00:05:10
User entered '2010'	System	13 Oct 2020 20:47:39

US3632127

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 00:05:10
User entered empty.	System	13 Oct 2020 20:47:39

US3632127

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 00:05:10
User entered empty.	System	13 Oct 2020 20:47:39

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:39:51
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:49:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:49:23
Data point term sent to Coder	System	13 Oct 2020 20:48:27
User entered 'Osteoarthritis'	(b) (4), (b) (6)	13 Oct 2020 20:47:51

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:39:51
User entered '1 UNK 2003'	(b) (4), (b) (6)	13 Oct 2020 20:47:51

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:39:51
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:47:51

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:39:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:47:51

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:39:51
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:47:51

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:39:51
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:47:51

US3632127

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 00:05:10
User entered 'Jan 2003'	System	13 Oct 2020 20:47:51

US3632127

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 00:05:10
User entered '2003'	System	13 Oct 2020 20:47:51

US3632127

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 00:05:10
User entered empty.	System	13 Oct 2020 20:47:51

US3632127

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 00:05:10
User entered empty.	System	13 Oct 2020 20:47:51

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:39:54
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. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 07:23:11
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. ' answered with 'Participant takes Vitamin D3 for bone health and uses Voltaren Gel as needed on your ankles. Medications are being adding to the conmed.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 16:09:54
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. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 07:44:38
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Rheumatoid arthropathies, PT: Rheumatoid arthritis, LLT: Rheumatoid arthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 05:23:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 05:23:22
Data point term sent to Coder System	System	13 Oct 2020 20:48:27
User entered 'Rheumatoid Arthritis (both ankles)'	(b) (4), (b) (6)	13 Oct 2020 20:48:12

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:39:54
User entered '1 UNK 2016'	(b) (4), (b) (6)	13 Oct 2020 20:48:12

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:39:54
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:48:12

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:39:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:48:12

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:39:54
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:48:12

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:39:54
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:48:12

US3632127

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 00:05:10
User entered 'Jan 2016'	System	13 Oct 2020 20:48:12

US3632127

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 00:05:10
User entered '2016'	System	13 Oct 2020 20:48:12

US3632127

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 00:05:10
User entered empty.	System	13 Oct 2020 20:48:12

US3632127

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 00:05:10
User entered empty.	System	13 Oct 2020 20:48:12

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:39:56
User coded data point as SOC: Infections and infestations, HLT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes simplex, LLT: Herpes simplex - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:50:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:50:16
Data point term sent to Coder	System	13 Oct 2020 20:49:28
User entered 'Herpes Simplex Virus'	(b) (4), (b) (6)	13 Oct 2020 20:48:46

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:39:56
User entered '1 UNK 2012'	(b) (4), (b) (6)	13 Oct 2020 20:48:46

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:39:56
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:48:46

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:39:56
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 12:26:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 12:26:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	14 Oct 2020 12:26:41
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 20:48:46
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:48:46

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:39:56
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:48:46

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:39:56
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:48:46

US3632127

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 00:05:10
User entered 'Jan 2012'	System	13 Oct 2020 20:48:46

US3632127

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 00:05:10
User entered '2012'	System	13 Oct 2020 20:48:46

US3632127

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 00:05:10
User entered empty.	System	13 Oct 2020 20:48:46

US3632127

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 00:05:10
User entered empty.	System	13 Oct 2020 20:48:46

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:42:26
User coded data point as SOC: Surgical and medical procedures, HLG: Gastrointestinal therapeutic procedures, HLT: Small intestine therapeutic procedures, PT: Small intestine operation, LLT: Small intestine operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 08:19:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 08:19:26
Data point term sent to Coder	System	13 Oct 2020 20:49:33
User entered 'Small Bowel Surgery'	(b) (4), (b) (6)	13 Oct 2020 20:49:08

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:42:26
User entered '1 UNK 1994'	(b) (4), (b) (6)	13 Oct 2020 20:49:08

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:42:26
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:49:08

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:42:26
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	14 Oct 2020 12:32:09
User entered 'No (N)' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	14 Oct 2020 12:32:09
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	13 Oct 2020 20:49:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:49:08

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:42:26
User entered '1 UNK 1994'	(b) (4), (b) (6)	13 Oct 2020 20:49:08

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:42:26
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:49:08

US3632127

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 00:05:10
User entered 'Jan 1994'	System	13 Oct 2020 20:49:08

US3632127

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 00:05:10
User entered '1994'	System	13 Oct 2020 20:49:08

US3632127

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 00:05:10
User entered 'Jan 1994'	System	13 Oct 2020 20:49:08

US3632127

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 00:05:10
User entered '1994'	System	13 Oct 2020 20:49:08

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:41:48
User coded data point as SOC: Surgical and medical procedures, HLG: Gastrointestinal therapeutic procedures, HLT: Small intestine therapeutic procedures, PT: Small intestinal resection, LLT: Small bowel resection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 12:53:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 12:53:30
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 05:41:28
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'Participant believes this was due to blockage, participant was not sure of the reason or condition that led to procedure. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 16:09:13
Data point term sent to Coder	System	03 Nov 2020 16:08:52
Coding entries removed.	(b) (4), (b) (6)	03 Nov 2020 16:08:44
User entered 'SMALL BOWEL REPAIR due to blockage' reason for change: Per Query Resolution	(b) (4), (b) (6)	03 Nov 2020 16:08:44
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 07:47:06
User coded data point as SOC: Surgical and medical procedures, HLG: Gastrointestinal therapeutic procedures, HLT: Small intestine therapeutic procedures, PT: Small intestine operation, LLT: Small intestine operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 08:21:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 08:21:23

US3632127

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:08:05

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	13 Oct 2020 20:49:34
User entered 'Small Bowel Repair'	(b) (4), (b) (6)	13 Oct 2020 20:49:30

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:41:48
User entered '1 UNK 2013'	(b) (4), (b) (6)	13 Oct 2020 20:49:30

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:41:48
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:49:30

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:41:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:49:30

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:41:48
User entered '1 UNK 2013'	(b) (4), (b) (6)	13 Oct 2020 20:49:30

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:41:48
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:49:30

US3632127

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 00:05:10
User entered 'Jan 2013'	System	13 Oct 2020 20:49:30

US3632127

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 00:05:10
User entered '2013'	System	13 Oct 2020 20:49:30

US3632127

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 00:05:10
User entered 'Jan 2013'	System	13 Oct 2020 20:49:30

US3632127

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 00:05:10
User entered '2013'	System	13 Oct 2020 20:49:30

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:41:51
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:51:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:51:19
Data point term sent to Coder	System	13 Oct 2020 20:50:37
User entered 'Constipation'	(b) (4), (b) (6)	13 Oct 2020 20:49:42

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:41:51
User entered '1 UNK 1994'	(b) (4), (b) (6)	13 Oct 2020 20:49:42

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:41:51
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:49:42

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:41:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:49:42

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:41:51
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:49:42

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:41:51
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:49:42

US3632127

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 00:05:10
User entered 'Jan 1994'	System	13 Oct 2020 20:49:42

US3632127

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 00:05:10
User entered '1994'	System	13 Oct 2020 20:49:42

US3632127

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 00:05:10
User entered empty.	System	13 Oct 2020 20:49:42

US3632127

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 00:05:10
User entered empty.	System	13 Oct 2020 20:49:42

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:41:55
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:51:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:51:20
Data point term sent to Coder	System	13 Oct 2020 20:50:39
User entered 'Post Menopausal'	(b) (4), (b) (6)	13 Oct 2020 20:50:01

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:41:55
User entered '1 UNK 2006'	(b) (4), (b) (6)	13 Oct 2020 20:50:01

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:41:55
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:50:01

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:41:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:50:01

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:41:55
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:50:01

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:41:55
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:50:01

US3632127

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 00:05:10
User entered 'Jan 2006'	System	13 Oct 2020 20:50:01

US3632127

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 00:05:10
User entered '2006'	System	13 Oct 2020 20:50:01

US3632127

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 00:05:10
User entered empty.	System	13 Oct 2020 20:50:01

US3632127

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 00:05:10
User entered empty.	System	13 Oct 2020 20:50:01

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:46:26
DataPoint Un-verified.	(b) (4), (b) (6)	24 Feb 2021 16:46:23
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 16:41:59
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Oct 2020 04:22:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Oct 2020 04:22:24
Data point term sent to Coder	System	23 Oct 2020 18:54:02
User entered 'SEVERE OBESITY (BMI 42.13479)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 18:53:38
User entered 'Severe Obesity'	(b) (4), (b) (6)	23 Oct 2020 18:53:25

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:46:26
DataPoint Un-verified.	(b) (4), (b) (6)	24 Feb 2021 16:46:23
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 16:41:59
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 18:53:25

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:46:26
DataPoint Un-verified.	(b) (4), (b) (6)	24 Feb 2021 16:46:23
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 16:41:59
User entered '1'	(b) (4), (b) (6)	23 Oct 2020 18:53:25

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:46:26
DataPoint Un-verified.	(b) (4), (b) (6)	24 Feb 2021 16:46:23
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 16:41:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 18:53:25

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:46:26
DataPoint Un-verified.	(b) (4), (b) (6)	24 Feb 2021 16:46:23
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 16:41:59
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 18:53:25

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:46:26
DataPoint Un-verified.	(b) (4), (b) (6)	24 Feb 2021 16:46:23
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 16:41:59
User entered '0'	(b) (4), (b) (6)	23 Oct 2020 18:53:25

US3632127

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 00:05:10
User entered empty.	System	23 Oct 2020 18:53:25

US3632127

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 00:05:10
User entered empty.	System	23 Oct 2020 18:53:25

US3632127

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 00:05:10
User entered empty.	System	23 Oct 2020 18:53:25

US3632127

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 00:05:10
User entered empty.	System	23 Oct 2020 18:53:25

US3632127

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 00:05:10
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:45:41
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
User closed query 'Per MM, please clarify the MH term ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:04:49
User coded data point as SOC: Investigations, HLG: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: Cholesterol high - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 17:23:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 17:23:59
Data point term sent to Coder	System	24 Feb 2021 17:23:19
Query 'Per MM, please clarify the MH term ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 17:22:32
DataPoint Un-verified.	(b) (4), (b) (6)	24 Feb 2021 17:22:26
Coding entries removed.	(b) (4), (b) (6)	24 Feb 2021 17:22:26
User entered 'ELEVATED CHOLESTEROL' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 17:22:26
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 16:46:40
User opened query 'Per MM, please clarify the MH term ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 14:55:30
User coded data point as SOC: Investigations, HLG: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: Blood cholesterol increased - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Jan 2021 13:47:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Jan 2021 13:47:10
Data point term sent to Coder	System	15 Jan 2021 15:36:00
User entered 'Slightly Elevated Cholesterol'	(b) (4), (b) (6)	15 Jan 2021 15:35:41

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:46:40
User entered 'UN Feb 2017'	(b) (4), (b) (6)	15 Jan 2021 15:35:41

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:46:40
User entered '0'	(b) (4), (b) (6)	15 Jan 2021 15:35:41

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:46:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Jan 2021 15:35:41

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:46:40
User entered empty.	(b) (4), (b) (6)	15 Jan 2021 15:35:41

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:46:40
User entered '0'	(b) (4), (b) (6)	15 Jan 2021 15:35:41

US3632127

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 00:05:10
User entered 'Feb 2017'	System	15 Jan 2021 15:35:41

US3632127

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 00:05:10
User entered '2017'	System	15 Jan 2021 15:35:41

US3632127

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 00:05:10
User entered empty.	System	15 Jan 2021 15:35:41

US3632127

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 00:05:10
User entered empty.	System	15 Jan 2021 15:35:41

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:48:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:43:47

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:48:05
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 20:43:47

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:48:05
User entered '12:09'	(b) (4), (b) (6)	13 Oct 2020 20:43:47

US3632127

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 00:05:10
User entered '13 Oct 2020 12:09'	System	13 Oct 2020 20:43:47

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:48:05
User entered '64.5' in	(b) (4), (b) (6)	13 Oct 2020 20:43:47
DataPoint set to visible.	System	13 Oct 2020 17:58:39

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:48:05
User entered '248.8' lb	(b) (4), (b) (6)	13 Oct 2020 20:43:47
DataPoint set to visible.	System	13 Oct 2020 17:58:39

US3632127

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 00:05:10
User closed query 'Per CDM: Please confirm if Height and Weight values are correct. BMI suggests patient has Severe Obesity. If so, please update Medical History. Thank you' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 05:50:22
Query 'Per CDM: Please confirm if Height and Weight values are correct. BMI suggests patient has Severe Obesity. If so, please update Medical History. Thank you' answered with 'Medical Hx updated' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 18:53:09
User opened query 'Per CDM: Please confirm if Height and Weight values are correct. BMI suggests patient has Severe Obesity. If so, please update Medical History. Thank you' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 19:36:07
User entered '42.13479'	System	13 Oct 2020 20:43:47
DataPoint set to visible.	System	13 Oct 2020 17:58:39

US3632127

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 00:05:10
User entered 'kg/m2'	System	13 Oct 2020 20:43:47
DataPoint set to visible.	System	13 Oct 2020 17:58:39

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:48:05
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Oct 2020 20:43:47

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:48:05
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:43:47

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:48:05
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:43:47

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:48:05
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Oct 2020 20:43:47

US3632127

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 00:05:10
User entered 'bpm'	System	13 Oct 2020 20:43:47

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:48:05
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Oct 2020 20:43:47

US3632127

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 00:05:10
User entered 'breaths/min'	System	13 Oct 2020 20:43:47

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:48:05
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Oct 2020 20:43:47

US3632127

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 00:05:10
User entered 'mmHg'	System	13 Oct 2020 20:43:47

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:48:05
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Oct 2020 20:43:47

US3632127

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 00:05:10
User entered 'mmHg'	System	13 Oct 2020 20:43:47

US3632127

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 00:05:10

US3632127

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 00:05:10

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:51:19
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:59:05

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:51:19
User entered '13 Oct 2020'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:59:05

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:51:24
User entered '13 Oct 2020'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:59:30

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:51:24
User entered 'No (N)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:59:30

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:51:24
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:59:30

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:51:24
User entered empty.	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:59:30

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:51:24
User entered empty.	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:59:30

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:51:24
User entered '0'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:59:30

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:51:24
User entered '01 UNK 2006'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:59:30

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:51:24
User entered '0'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:59:30

US3632127

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 00:05:10
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:48:54
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 16:01:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Feb 2021 16:53:05
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 16:52:28
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 18:01:24
User entered 'No (N)' reason for change: Data Entry Error	Kelly Likos (b) (4)	13 Oct 2020 18:01:24
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:03
User entered empty.	Kelly Likos (b) (4)	13 Oct 2020 18:01:03
	(b) (4)	

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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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:52:28
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 18:01:24
User entered 'No (N)' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:24
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:03
User entered empty.	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:03

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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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:52:28
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 18:01:24
User entered 'No (N)' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:24
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:03
User entered empty.	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:03

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:52:28
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 18:01:24
User entered 'No (N)' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:24
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:03
User entered empty.	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:03

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:52:28
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 18:01:24
User entered 'No (N)' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:24
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:03
User entered empty.	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:03

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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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:52:28
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 18:01:24
User entered 'No (N)' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:24
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:03
User entered empty.	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:03

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:52:28
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 18:01:24
User entered 'No (N)' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:24
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:03
User entered empty.	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:03

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:52:28
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:03

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:52:28
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 18:01:24
User entered 'No (N)' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:24
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:03
User entered empty.	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:03

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:52:28
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 18:01:24
User entered 'No (N)' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:24
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:03
User entered empty.	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:03

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:52:28
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 18:01:24
User entered 'No (N)' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:24
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:03
User entered empty.	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:03

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:52:28
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:03

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:52:28
User entered 'Home Healthcare Worker'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:03

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
User entered '0'	(b) (4) Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:03

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:52:28
User entered '0'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:03

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:52:28
User entered '0'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:03

US3632127

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 00:05:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:15:11
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:01:50
DataPoint Un-verified.	(b) (4), (b) (6)	24 Feb 2021 16:54:07
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 16:52:28
User entered '0'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:03

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:52:28
User entered '0'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:03

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:52:28
User entered '0'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:03

US3632127

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 00:05:10
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
User entered '1'	(b) (4) Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:03

US3632127

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 00:05:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:15:20
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:37:15
User closed query 'This was not noted in the source; please review/verify and update EDC if applicable.' (Site from CRA).	(b) (4)	
Query 'This was not noted in the source; please review/verify and update EDC if applicable.' answered with 'listed in source as a checked box, also added it to "other details" section' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 17:04:55
Signature has been broken.	Aastha KC (b) (4)	07 Apr 2021 17:08:48
User entered 'RESIDENT IN A COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION- 4 room house' reason for change:	(b) (4)	
Data Entry Error	Aastha KC (b) (4)	07 Apr 2021 17:08:29
User opened query 'This was not noted in the source; please review/verify and update EDC if applicable.' (Site from CRA).	(b) (4)	
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:22:47
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 16:01:50
User entered 'Resident in a community with ongoing person to person transmission' reason for change:	(b) (4), (b) (6)	25 Feb 2021 16:01:50
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 16:52:28
User entered 'Multi room residential home'	Kelly Likos (b) (4)	13 Oct 2020 18:01:03
	(b) (4)	

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:00:30
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:15:02

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:00:30
User entered '13 Oct 2020'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:15:02

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:00:30
User entered 'Clinic (Clinic)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:15:02

US3632127

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)	28 Mar 2021 01:33:19
User entered 'VISIT1'	System	13 Oct 2020 18:15:02

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:07:18
User entered '13 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Oct 2020 17:03:44

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:07:18
User entered '146895'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Oct 2020 17:03:44

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:07:18
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Oct 2020 17:03:44

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:07:18
User entered 'No (N)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:46

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:07:18
User entered 'No (N)' reason for change: Data Entry Error	Kelly Likos (b) (4)	14 Oct 2020 12:18:48
User entered 'Yes (Y)'	(b) (4) Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:46

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:07:18
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:46

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:07:18
User entered 'No (N)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:46

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:07:18
User entered 'No (N)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:46

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:07:18
User entered 'No (N)'	Kelly Likos (b) (4)	13 Oct 2020 18:01:46
DataPoint set to visible.	(b) (4) System	13 Oct 2020 17:58:31

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:07:48
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:07:50
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:07:48
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:07:50
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:07:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:07:55
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:07:55
User entered '12:09'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User entered '13 Oct 2020 12:09'	System	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:07:55
User entered '98.5' F	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:07:55
User entered 'Oral (Oral)'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:07:55
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:07:55
User entered '72'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User entered 'bpm'	System	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:07:55
User entered '12'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User entered 'breaths/min'	System	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:07:55
User entered '126'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User entered 'mmHg'	System	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:07:55
User entered '87'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User entered 'mmHg'	System	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:07:48
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:07:50
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:09:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:09:13
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:09:13
User entered '14:40'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User entered '13 Oct 2020 14:40'	System	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:09:13
User entered '98.7' F	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:09:13
User entered 'Oral (Oral)'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:09:13
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:09:13
User entered '70'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User entered 'bpm'	System	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:09:13
User entered '12'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User entered 'breaths/min'	System	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:09:13
User entered '116'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User entered 'mmHg'	System	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:09:13
User entered '74'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User entered 'mmHg'	System	13 Oct 2020 20:46:24

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:09:24
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:02:17

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:09:24
User entered '13 Oct 2020'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:02:17

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:09:31
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:14:30

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:09:31
User entered empty.	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:14:30

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:09:31
User entered empty.	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:14:30

US3632127

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)	28 Mar 2021 01:33:19
User entered 'MRNA-1273 OR PLACEBO'	System	13 Oct 2020 18:14:30

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:09:31
User entered '13 Oct 2020'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:14:30

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:09:31
User entered '14:10'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:14:30

US3632127

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)	28 Mar 2021 01:33:19
User entered '13 Oct 2020 14:10'	System	13 Oct 2020 18:14:30

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:09:31
User entered 'Left Arm (LEFT ARM)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:14:30

US3632127

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)	28 Mar 2021 01:33:19
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:09:31
User entered 'ONCE'	System	13 Oct 2020 18:14:30

US3632127

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)	28 Mar 2021 01:33:19
User entered 'INTRAMUSCULAR'	System	13 Oct 2020 18:14:30

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:09:50
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:17:03

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:09:50
User entered '13 Oct 2020'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:17:03

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:09:50
User entered '12:59'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:17:03

US3632127

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)	28 Mar 2021 01:33:19
User entered '13 Oct 2020 12:59'	System	13 Oct 2020 18:17:03

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:10:05
User entered '13 Oct 2020'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:17:21

US3632127

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)	28 Mar 2021 01:33:19
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:17:21

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:10:05
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:17:21

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:10:05
User entered '13:06'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:17:21

US3632127

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)	28 Mar 2021 01:33:19
User entered '13 Oct 2020 13:06'	System	13 Oct 2020 18:17:21

US3632127

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)	28 Mar 2021 01:33:19
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:17:21

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:10:05
User entered 'No (N)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:17:21

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:10:05
User entered empty.	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:17:21

US3632127

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)	28 Mar 2021 01:33:19
User entered empty.	System	13 Oct 2020 18:17:21

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:10:13
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:18:09

US3632127

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)	28 Mar 2021 01:33:19
User entered '1'	System	13 Oct 2020 18:18:09

US3632127

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 11:39:14
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T14:41:24', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'db35cadc-a595-4922-b1fc-a0ecff557427'	System	13 Oct 2020 18:41:50
User entered 'Yes (Y)'	System	13 Oct 2020 18:41:50

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T14:41:35', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'db35cadc-a595-4922-b1fc-a0ecff557427' User entered '98.7'	System	13 Oct 2020 18:41:50
	System	13 Oct 2020 18:41:50

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T14:41:40', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'db35cadc-a595-4922-b1fc-a0ecff557427'	System	13 Oct 2020 18:41:50
User entered 'No (N)'	System	13 Oct 2020 18:41:50

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T14:41:47', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'db35cadc-a595-4922-b1fc-a0ecff557427' User entered '13 Oct 2020 14:41'	System	13 Oct 2020 18:41:50
	System	13 Oct 2020 18:41:50

US3632127

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 11:39:14
User entered '13 Oct 2020 14:30'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
User entered '13 Oct 2020 17:00'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:35:48', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '78dbd2ec-3055-4f99-8fab-9a0fd58c3bbb' User entered 'Yes (Y)'	System	13 Oct 2020 23:37:24
	System	13 Oct 2020 23:37:24

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:36:49', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '78dbd2ec-3055-4f99-8fab-9a0fd58c3bbb' User entered '99.3'	System	13 Oct 2020 23:37:24
	System	13 Oct 2020 23:37:24

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:37:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '78dbd2ec-3055-4f99-8fab-9a0fd58c3bbb' User entered 'Yes (Y)'	System	13 Oct 2020 23:37:24
	System	13 Oct 2020 23:37:24

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

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 11:39:14
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 'was contacted and eCRFs has been updated' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 07:23:21
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).	Bezuayehu Mandefro (b) (4)	20 Oct 2020 15:16:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:37:10', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '78dbd2ec-3055-4f99-8fab-9a0fd58c3bbb'	System	13 Oct 2020 23:37:24
User entered '1'	System	13 Oct 2020 23:37:24

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:37:10', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '78dbd2ec-3055-4f99-8fab-9a0fd58c3bbb' User entered '0'	System	13 Oct 2020 23:37:24
	System	13 Oct 2020 23:37:24

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:37:21', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '78dbd2ec-3055-4f99-8fab-9a0fd58c3bbb' User entered '13 Oct 2020 19:37'	System	13 Oct 2020 23:37:24
	System	13 Oct 2020 23:37:24

US3632127

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 11:39:14
User entered '13 Oct 2020 17:55'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 2'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-14T18:59:19', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8882121f-0f49-4315-a102-9a018c027de9' User entered 'Yes (Y)'	System	14 Oct 2020 22:59:43
	System	14 Oct 2020 22:59:43

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-14T18:59:26', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8882121f-0f49-4315-a102-9a018c027de9' User entered '98.5'	System	14 Oct 2020 22:59:43
	System	14 Oct 2020 22:59:43

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-14T18:59:31', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8882121f-0f49-4315-a102-9a018c027de9' User entered 'No (N)'	System	14 Oct 2020 22:59:43
	System	14 Oct 2020 22:59:43

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-14T18:59:38', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8882121f-0f49-4315-a102-9a018c027de9' User entered '14 Oct 2020 18:59'	System	14 Oct 2020 22:59:43
	System	14 Oct 2020 22:59:43

US3632127

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 11:39:14
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 3'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-15T18:12:41', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a21844ba-dcc3-483e-bcc9-dbd1dd09a5f5' User entered 'Yes (Y)'	System	15 Oct 2020 22:13:11
	System	15 Oct 2020 22:13:11

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-15T18:13:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a21844ba-dcc3-483e-bcc9-dbd1dd09a5f5' User entered '97.5'	System	15 Oct 2020 22:13:11
	System	15 Oct 2020 22:13:11

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-15T18:13:04', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a21844ba-dcc3-483e-bcc9-dbd1dd09a5f5'	System	15 Oct 2020 22:13:11
User entered 'No (N)'	System	15 Oct 2020 22:13:11

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-15T18:13:08', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a21844ba-dcc3-483e-bcc9-dbd1dd09a5f5' User entered '15 Oct 2020 18:13'	System	15 Oct 2020 22:13:11
	System	15 Oct 2020 22:13:11

US3632127

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 11:39:14
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 4'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-16T19:02:22', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8956e9fa-eb03-4509-a0e1-43f8f155fe9f' User entered 'Yes (Y)'	System	16 Oct 2020 23:03:26
	System	16 Oct 2020 23:03:26

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-16T19:03:15', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8956e9fa-eb03-4509-a0e1-43f8f155fe9f' User entered '98.4'	System	16 Oct 2020 23:03:26
	System	16 Oct 2020 23:03:26

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-16T19:03:19', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8956e9fa-eb03-4509-a0e1-43f8f155fe9f' User entered 'No (N)'	System	16 Oct 2020 23:03:26
	System	16 Oct 2020 23:03:26

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-16T19:03:22', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8956e9fa-eb03-4509-a0e1-43f8f155fe9f' User entered '16 Oct 2020 19:03'	System	16 Oct 2020 23:03:26
	System	16 Oct 2020 23:03:26

US3632127

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 11:39:14
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 5'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-17T18:19:20', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ac8ad103-2938-444e-b3bd-4d0ced4f9f77'	System	17 Oct 2020 22:20:27
User entered 'Yes (Y)'	System	17 Oct 2020 22:20:27

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-17T18:20:18', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ac8ad103-2938-444e-b3bd-4d0ced4f9f77' User entered '99.1'	System	17 Oct 2020 22:20:27
	System	17 Oct 2020 22:20:27

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-17T18:20:21', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ac8ad103-2938-444e-b3bd-4d0ced4f9f77'	System	17 Oct 2020 22:20:27
User entered 'No (N)'	System	17 Oct 2020 22:20:27

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-17T18:20:25', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ac8ad103-2938-444e-b3bd-4d0ced4f9f77' User entered '17 Oct 2020 18:20'	System	17 Oct 2020 22:20:27
	System	17 Oct 2020 22:20:27

US3632127

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 11:39:14
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 6'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-18T18:10:21', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e28ba8c6-3c08-4a11-bcd5-cd565e536f75' User entered 'Yes (Y)'	System	18 Oct 2020 22:10:51
	System	18 Oct 2020 22:10:51

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-18T18:10:40', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e28ba8c6-3c08-4a11-bcd5-cd565e536f75' User entered '99.2'	System	18 Oct 2020 22:10:51
	System	18 Oct 2020 22:10:51

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-18T18:10:43', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e28ba8c6-3c08-4a11-bcd5-cd565e536f75'	System	18 Oct 2020 22:10:51
User entered 'No (N)'	System	18 Oct 2020 22:10:51

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-18T18:10:48', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e28ba8c6-3c08-4a11-bcd5-cd565e536f75' User entered '18 Oct 2020 18:10'	System	18 Oct 2020 22:10:51
	System	18 Oct 2020 22:10:51

US3632127

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 11:39:14
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 7'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-19T18:19:52', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e9f0b0fa-af25-4f7b-8001-9c7f3758aa97'	System	19 Oct 2020 22:21:00
User entered 'Yes (Y)'	System	19 Oct 2020 22:21:00

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-19T18:20:49', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e9f0b0fa-af25-4f7b-8001-9c7f3758aa97' User entered '98.1'	System	19 Oct 2020 22:21:00
	System	19 Oct 2020 22:21:00

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-19T18:20:53', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e9f0b0fa-af25-4f7b-8001-9c7f3758aa97'	System	19 Oct 2020 22:21:00
User entered 'No (N)'	System	19 Oct 2020 22:21:00

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-19T18:20:56', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e9f0b0fa-af25-4f7b-8001-9c7f3758aa97'	System	19 Oct 2020 22:21:00
User entered '19 Oct 2020 18:20'	System	19 Oct 2020 22:21:00

US3632127

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 11:39:14
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T14:42:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8a0fdd7f-3545-4391-8f2a-ebec1263a7a3'	System	13 Oct 2020 18:42:47
User entered 'None (1)'	System	13 Oct 2020 18:42:47

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T14:42:14', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8a0fdd7f-3545-4391-8f2a-ebee1263a7a3' User entered 'No (N)'	System	13 Oct 2020 18:42:47
	System	13 Oct 2020 18:42:47

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T14:42:22', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8a0fdd7f-3545-4391-8f2a-ebee1263a7a3' User entered 'No (N)'	System	13 Oct 2020 18:42:47
	System	13 Oct 2020 18:42:47

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T14:42:35', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8a0fdd7f-3545-4391-8f2a-ebec1263a7a3'	System	13 Oct 2020 18:42:47
User entered 'None (1)'	System	13 Oct 2020 18:42:47

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T14:42:42', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8a0fdd7f-3545-4391-8f2a-ebee1263a7a3' User entered '13 Oct 2020 14:42'	System	13 Oct 2020 18:42:47
	System	13 Oct 2020 18:42:47

US3632127

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 11:39:14
User entered '13 Oct 2020 14:30'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
User entered '13 Oct 2020 17:00'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:37:39', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '593cab0f-aa92-4da5-9962-5107c441b7a6'	System	13 Oct 2020 23:38:08
User entered 'None (1)'	System	13 Oct 2020 23:38:08

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:37:44', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '593cab0f-aa92-4da5-9962-5107c441b7a6'	System	13 Oct 2020 23:38:08
User entered 'No (N)'	System	13 Oct 2020 23:38:08

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:37:54', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '593cab0f-aa92-4da5-9962-5107c441b7a6' User entered 'No (N)'	System	13 Oct 2020 23:38:08
	System	13 Oct 2020 23:38:08

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:38:02', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '593cab0f-aa92-4da5-9962-5107c441b7a6'	System	13 Oct 2020 23:38:08
User entered 'None (1)'	System	13 Oct 2020 23:38:08

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:38:06', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '593cab0f-aa92-4da5-9962-5107c441b7a6' User entered '13 Oct 2020 19:38'	System	13 Oct 2020 23:38:08
	System	13 Oct 2020 23:38:08

US3632127

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 11:39:14
User entered '13 Oct 2020 17:55'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 2'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-14T18:59:47', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '516e9c2a-0632-4ac9-968d-471329e04106' User entered 'None (1)'	System	14 Oct 2020 23:00:08
	System	14 Oct 2020 23:00:08

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-14T18:59:50', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '516e9c2a-0632-4ac9-968d-471329e04106' User entered 'No (N)'	System	14 Oct 2020 23:00:08
	System	14 Oct 2020 23:00:08

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-14T18:59:54', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '516e9c2a-0632-4ac9-968d-471329e04106' User entered 'No (N)'	System	14 Oct 2020 23:00:08
	System	14 Oct 2020 23:00:08

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-14T19:00:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '516e9c2a-0632-4ac9-968d-471329e04106'	System	14 Oct 2020 23:00:08
User entered 'None (1)'	System	14 Oct 2020 23:00:08

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-14T19:00:04', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '516e9c2a-0632-4ac9-968d-471329e04106' User entered '14 Oct 2020 19:00'	System	14 Oct 2020 23:00:08
	System	14 Oct 2020 23:00:08

US3632127

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 11:39:14
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 3'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-15T18:13:16', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8c43d413-aa76-4c71-b84d-0db1381b8b44'	System	15 Oct 2020 22:13:37
User entered 'None (1)'	System	15 Oct 2020 22:13:37

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-15T18:13:20', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8c43d413-aa76-4c71-b84d-0db1381b8b44'	System	15 Oct 2020 22:13:37
User entered 'No (N)'	System	15 Oct 2020 22:13:37

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-15T18:13:23', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8c43d413-aa76-4c71-b84d-0db1381b8b44'	System	15 Oct 2020 22:13:37
User entered 'No (N)'	System	15 Oct 2020 22:13:37

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-15T18:13:32', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8c43d413-aa76-4c71-b84d-0db1381b8b44'	System	15 Oct 2020 22:13:37
User entered 'None (1)'	System	15 Oct 2020 22:13:37

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-15T18:13:35', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8c43d413-aa76-4c71-b84d-0db1381b8b44' User entered '15 Oct 2020 18:13'	System	15 Oct 2020 22:13:37
	System	15 Oct 2020 22:13:37

US3632127

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 11:39:14
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 4'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-16T19:03:28', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '785ab381-c5da-4e66-adab-769a31973459'	System	16 Oct 2020 23:03:48
User entered 'None (1)'	System	16 Oct 2020 23:03:48

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-16T19:03:31', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '785ab381-c5da-4e66-adab-769a31973459'	System	16 Oct 2020 23:03:48
User entered 'No (N)'	System	16 Oct 2020 23:03:48

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-16T19:03:35', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '785ab381-c5da-4e66-adab-769a31973459' User entered 'No (N)'	System	16 Oct 2020 23:03:48
	System	16 Oct 2020 23:03:48

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-16T19:03:43', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '785ab381-c5da-4e66-adab-769a31973459'	System	16 Oct 2020 23:03:48
User entered 'None (1)'	System	16 Oct 2020 23:03:48

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-16T19:03:46', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '785ab381-c5da-4e66-adab-769a31973459' User entered '16 Oct 2020 19:03'	System	16 Oct 2020 23:03:48
	System	16 Oct 2020 23:03:48

US3632127

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 11:39:14
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 5'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-17T18:20:52', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '3e82052a-e29e-47f3-b811-52e0b2f3c57d'	System	17 Oct 2020 22:21:35
User entered 'None (1)'	System	17 Oct 2020 22:21:35

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-17T18:20:57', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '3e82052a-e29e-47f3-b811-52e0b2f3c57d' User entered 'No (N)'	System	17 Oct 2020 22:21:35
	System	17 Oct 2020 22:21:35

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-17T18:21:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '3e82052a-e29e-47f3-b811-52e0b2f3c57d' User entered 'No (N)'	System	17 Oct 2020 22:21:35
	System	17 Oct 2020 22:21:35

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-17T18:21:23', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '3e82052a-e29e-47f3-b811-52e0b2f3c57d'	System	17 Oct 2020 22:21:35
User entered 'None (1)'	System	17 Oct 2020 22:21:35

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-17T18:21:28', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '3e82052a-e29e-47f3-b811-52e0b2f3c57d' User entered '17 Oct 2020 18:21'	System	17 Oct 2020 22:21:35
	System	17 Oct 2020 22:21:35

US3632127

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 11:39:14
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 6'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-18T18:10:59', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a72e4769-d95c-4c43-af90-afe615edaac3'	System	18 Oct 2020 22:11:30
User entered 'None (1)'	System	18 Oct 2020 22:11:30

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-18T18:11:02', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a72e4769-d95c-4c43-af90-afe615edaac3'	System	18 Oct 2020 22:11:30
User entered 'No (N)'	System	18 Oct 2020 22:11:30

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-18T18:11:06', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a72e4769-d95c-4c43-af90-afe615edaac3' User entered 'No (N)'	System	18 Oct 2020 22:11:30
	System	18 Oct 2020 22:11:30

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-18T18:11:23', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a72e4769-d95c-4c43-af90-afe615edaac3'	System	18 Oct 2020 22:11:30
User entered 'None (1)'	System	18 Oct 2020 22:11:30

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-18T18:11:28', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a72e4769-d95c-4c43-af90-afe615edaac3' User entered '18 Oct 2020 18:11'	System	18 Oct 2020 22:11:30
	System	18 Oct 2020 22:11:30

US3632127

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 11:39:14
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 7'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-19T18:21:01', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7ec7591d-d917-44b3-8cc7-d0ea914a26d3'	System	19 Oct 2020 22:21:18
User entered 'None (1)'	System	19 Oct 2020 22:21:18

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-19T18:21:03', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7ec7591d-d917-44b3-8cc7-d0ea914a26d3' User entered 'No (N)'	System	19 Oct 2020 22:21:18
	System	19 Oct 2020 22:21:18

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-19T18:21:07', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7ec7591d-d917-44b3-8cc7-d0ea914a26d3' User entered 'No (N)'	System	19 Oct 2020 22:21:18
	System	19 Oct 2020 22:21:18

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-19T18:21:11', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7ec7591d-d917-44b3-8cc7-d0ea914a26d3'	System	19 Oct 2020 22:21:18
User entered 'None (1)'	System	19 Oct 2020 22:21:18

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-19T18:21:14', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7ec7591d-d917-44b3-8cc7-d0ea914a26d3' User entered '19 Oct 2020 18:21'	System	19 Oct 2020 22:21:18
	System	19 Oct 2020 22:21:18

US3632127

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 11:39:14
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T14:42:51', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '63290041-5a85-4e6e-8132-7bad7f7695e0' User entered 'None (0)'	System	13 Oct 2020 18:43:19
	System	13 Oct 2020 18:43:19

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T14:42:54', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '63290041-5a85-4e6e-8132-7bad7f7695e0' User entered 'None (0)'	System	13 Oct 2020 18:43:19
	System	13 Oct 2020 18:43:19

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T14:42:58', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '63290041-5a85-4e6e-8132-7bad7f7695e0' User entered 'None (0)'	System	13 Oct 2020 18:43:19
	System	13 Oct 2020 18:43:19

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T14:43:01', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '63290041-5a85-4e6e-8132-7bad7f7695e0' User entered 'None (0)'	System	13 Oct 2020 18:43:19
	System	13 Oct 2020 18:43:19

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T14:43:04', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '63290041-5a85-4e6e-8132-7bad7f7695e0' User entered 'None (0)'	System	13 Oct 2020 18:43:19
	System	13 Oct 2020 18:43:19

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T14:43:07', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '63290041-5a85-4e6e-8132-7bad7f7695e0' User entered 'None (0)'	System	13 Oct 2020 18:43:19
	System	13 Oct 2020 18:43:19

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T14:43:12', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '63290041-5a85-4e6e-8132-7bad7f7695e0' User entered 'No (N)'	System	13 Oct 2020 18:43:19
	System	13 Oct 2020 18:43:19

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T14:43:16', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '63290041-5a85-4e6e-8132-7bad7f7695e0' User entered '13 Oct 2020 14:43'	System	13 Oct 2020 18:43:19
	System	13 Oct 2020 18:43:19

US3632127

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 11:39:14
User entered '13 Oct 2020 14:30'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
User entered '13 Oct 2020 17:00'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:38:22', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7789e156-d355-4068-aeeb-ba09aa23eaa7'	System	13 Oct 2020 23:39:13
User entered 'No interference with activity (1)'	System	13 Oct 2020 23:39:13

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:38:27', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7789e156-d355-4068-aeeb-ba09aa23eaa7' User entered 'None (0)'	System	13 Oct 2020 23:39:13
	System	13 Oct 2020 23:39:13

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:38:40', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7789e156-d355-4068-aeeb-ba09aa23eaa7'	System	13 Oct 2020 23:39:13
User entered 'No interference with activity (1)'	System	13 Oct 2020 23:39:13

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:38:48', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7789e156-d355-4068-aeeb-ba09aa23eaa7'	System	13 Oct 2020 23:39:13
User entered 'No interference with activity (1)'	System	13 Oct 2020 23:39:13

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:38:52', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7789e156-d355-4068-aeeb-ba09aa23eaa7' User entered 'None (0)'	System	13 Oct 2020 23:39:13
	System	13 Oct 2020 23:39:13

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:38:57', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7789e156-d355-4068-aeeb-ba09aa23eaa7' User entered 'None (0)'	System	13 Oct 2020 23:39:13
	System	13 Oct 2020 23:39:13

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:39:04', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7789e156-d355-4068-aeeb-ba09aa23eaa7' User entered 'No (N)'	System	13 Oct 2020 23:39:13
	System	13 Oct 2020 23:39:13

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:39:08', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7789e156-d355-4068-aeeb-ba09aa23eaa7' User entered '13 Oct 2020 19:39'	System	13 Oct 2020 23:39:13
	System	13 Oct 2020 23:39:13

US3632127

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 11:39:14
User entered '13 Oct 2020 17:55'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 2'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-14T19:00:12', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7cc3697d-cad0-423b-8f07-e5e82a6851c1' User entered 'None (0)'	System	14 Oct 2020 23:00:40
	System	14 Oct 2020 23:00:40

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-14T19:00:15', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7cc3697d-cad0-423b-8f07-e5e82a6851c1' User entered 'None (0)'	System	14 Oct 2020 23:00:40
	System	14 Oct 2020 23:00:40

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-14T19:00:19', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7cc3697d-cad0-423b-8f07-e5e82a6851c1' User entered 'None (0)'	System	14 Oct 2020 23:00:40
	System	14 Oct 2020 23:00:40

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-14T19:00:22', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7cc3697d-cad0-423b-8f07-e5e82a6851c1' User entered 'None (0)'	System	14 Oct 2020 23:00:40
	System	14 Oct 2020 23:00:40

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-14T19:00:25', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7cc3697d-cad0-423b-8f07-e5e82a6851c1' User entered 'None (0)'	System	14 Oct 2020 23:00:40
	System	14 Oct 2020 23:00:40

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-14T19:00:30', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7cc3697d-cad0-423b-8f07-e5e82a6851c1' User entered 'None (0)'	System	14 Oct 2020 23:00:40
	System	14 Oct 2020 23:00:40

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-14T19:00:35', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7cc3697d-cad0-423b-8f07-e5e82a6851c1' User entered 'No (N)'	System	14 Oct 2020 23:00:40
	System	14 Oct 2020 23:00:40

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-14T19:00:38', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7cc3697d-cad0-423b-8f07-e5e82a6851c1' User entered '14 Oct 2020 19:00'	System	14 Oct 2020 23:00:40
	System	14 Oct 2020 23:00:40

US3632127

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 11:39:14
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 3'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-15T18:13:42', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'b93e6581-51b8-4800-ba8f-15d08c0440b8' User entered 'None (0)'	System	15 Oct 2020 22:14:28
	System	15 Oct 2020 22:14:28

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-15T18:13:49', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'b93e6581-51b8-4800-ba8f-15d08c0440b8' User entered 'None (0)'	System	15 Oct 2020 22:14:28
	System	15 Oct 2020 22:14:28

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-15T18:13:54', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'b93e6581-51b8-4800-ba8f-15d08c0440b8' User entered 'None (0)'	System	15 Oct 2020 22:14:28
	System	15 Oct 2020 22:14:28

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-15T18:14:07', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'b93e6581-51b8-4800-ba8f-15d08c0440b8' User entered 'None (0)'	System	15 Oct 2020 22:14:28
	System	15 Oct 2020 22:14:28

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-15T18:14:12', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'b93e6581-51b8-4800-ba8f-15d08c0440b8' User entered 'None (0)'	System	15 Oct 2020 22:14:28
	System	15 Oct 2020 22:14:28

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-15T18:14:15', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'b93e6581-51b8-4800-ba8f-15d08c0440b8' User entered 'None (0)'	System	15 Oct 2020 22:14:28
	System	15 Oct 2020 22:14:28

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-15T18:14:22', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'b93e6581-51b8-4800-ba8f-15d08c0440b8' User entered 'No (N)'	System	15 Oct 2020 22:14:28
	System	15 Oct 2020 22:14:28

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-15T18:14:25', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'b93e6581-51b8-4800-ba8f-15d08c0440b8' User entered '15 Oct 2020 18:14'	System	15 Oct 2020 22:14:28
	System	15 Oct 2020 22:14:28

US3632127

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 11:39:14
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 4'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-16T19:03:52', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '90b4e129-fd40-409a-a184-46364b25fe51' User entered 'None (0)'	System	16 Oct 2020 23:04:23
	System	16 Oct 2020 23:04:23

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-16T19:03:55', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '90b4e129-fd40-409a-a184-46364b25fe51' User entered 'None (0)'	System	16 Oct 2020 23:04:23
	System	16 Oct 2020 23:04:23

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-16T19:03:59', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '90b4e129-fd40-409a-a184-46364b25fe51' User entered 'None (0)'	System	16 Oct 2020 23:04:23
	System	16 Oct 2020 23:04:23

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-16T19:04:04', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '90b4e129-fd40-409a-a184-46364b25fe51' User entered 'None (0)'	System	16 Oct 2020 23:04:23
	System	16 Oct 2020 23:04:23

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-16T19:04:08', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '90b4e129-fd40-409a-a184-46364b25fe51' User entered 'None (0)'	System	16 Oct 2020 23:04:23
	System	16 Oct 2020 23:04:23

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-16T19:04:12', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '90b4e129-fd40-409a-a184-46364b25fe51' User entered 'None (0)'	System	16 Oct 2020 23:04:23
	System	16 Oct 2020 23:04:23

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-16T19:04:17', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '90b4e129-fd40-409a-a184-46364b25fe51' User entered 'No (N)'	System	16 Oct 2020 23:04:23
	System	16 Oct 2020 23:04:23

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-16T19:04:21', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '90b4e129-fd40-409a-a184-46364b25fe51' User entered '16 Oct 2020 19:04'	System	16 Oct 2020 23:04:23
	System	16 Oct 2020 23:04:23

US3632127

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 11:39:14
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 5'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-17T18:21:33', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '4ac760b3-e8a5-4f75-9a74-a0c3474ff47f' User entered 'None (0)'	System	17 Oct 2020 22:22:05
	System	17 Oct 2020 22:22:05

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-17T18:21:36', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '4ac760b3-e8a5-4f75-9a74-a0c3474ff47f' User entered 'None (0)'	System	17 Oct 2020 22:22:05
	System	17 Oct 2020 22:22:05

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-17T18:21:41', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '4ac760b3-e8a5-4f75-9a74-a0c3474ff47f' User entered 'None (0)'	System	17 Oct 2020 22:22:05
	System	17 Oct 2020 22:22:05

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-17T18:21:45', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '4ac760b3-e8a5-4f75-9a74-a0c3474ff47f' User entered 'None (0)'	System	17 Oct 2020 22:22:05
	System	17 Oct 2020 22:22:05

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-17T18:21:47', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '4ac760b3-e8a5-4f75-9a74-a0c3474ff47f' User entered 'None (0)'	System	17 Oct 2020 22:22:05
	System	17 Oct 2020 22:22:05

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-17T18:21:51', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '4ac760b3-e8a5-4f75-9a74-a0c3474ff47f' User entered 'None (0)'	System	17 Oct 2020 22:22:05
	System	17 Oct 2020 22:22:05

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-17T18:21:55', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '4ac760b3-e8a5-4f75-9a74-a0c3474ff47f' User entered 'No (N)'	System	17 Oct 2020 22:22:05
	System	17 Oct 2020 22:22:05

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-17T18:21:58', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '4ac760b3-e8a5-4f75-9a74-a0c3474ff47f' User entered '17 Oct 2020 18:21'	System	17 Oct 2020 22:22:05
	System	17 Oct 2020 22:22:05

US3632127

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 11:39:14
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 6'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-18T18:11:33', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'd0600627-3645-4b6f-9297-034c8036c7ee' User entered 'None (0)'	System	18 Oct 2020 22:12:11
	System	18 Oct 2020 22:12:11

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-18T18:11:36', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'd0600627-3645-4b6f-9297-034c8036c7ee' User entered 'None (0)'	System	18 Oct 2020 22:12:11
	System	18 Oct 2020 22:12:11

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-18T18:11:41', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'd0600627-3645-4b6f-9297-034c8036c7ee' User entered 'No interference with activity (1)'	System	18 Oct 2020 22:12:11
	System	18 Oct 2020 22:12:11

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-18T18:11:49', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'd0600627-3645-4b6f-9297-034c8036c7ee' User entered 'No interference with activity (1)'	System	18 Oct 2020 22:12:11
	System	18 Oct 2020 22:12:11

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-18T18:11:52', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'd0600627-3645-4b6f-9297-034c8036c7ee' User entered 'None (0)'	System	18 Oct 2020 22:12:11
	System	18 Oct 2020 22:12:11

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-18T18:11:55', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'd0600627-3645-4b6f-9297-034c8036c7ee' User entered 'None (0)'	System	18 Oct 2020 22:12:11
	System	18 Oct 2020 22:12:11

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-18T18:12:05', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'd0600627-3645-4b6f-9297-034c8036c7ee' User entered 'No (N)'	System	18 Oct 2020 22:12:11
	System	18 Oct 2020 22:12:11

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-18T18:12:09', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'd0600627-3645-4b6f-9297-034c8036c7ee' User entered '18 Oct 2020 18:12'	System	18 Oct 2020 22:12:11
	System	18 Oct 2020 22:12:11

US3632127

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 11:39:14
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 7'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-19T18:21:18', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '0f246fa8-a542-443c-b2d4-294c15dc5f75' User entered 'None (0)'	System	19 Oct 2020 22:21:48
	System	19 Oct 2020 22:21:48

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-19T18:21:21', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '0f246fa8-a542-443c-b2d4-294c15dc5f75' User entered 'None (0)'	System	19 Oct 2020 22:21:48
	System	19 Oct 2020 22:21:48

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-19T18:21:27', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '0f246fa8-a542-443c-b2d4-294c15dc5f75'	System	19 Oct 2020 22:21:48
User entered 'No interference with activity (1)'	System	19 Oct 2020 22:21:48

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-19T18:21:30', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '0f246fa8-a542-443c-b2d4-294c15dc5f75' User entered 'None (0)'	System	19 Oct 2020 22:21:48
	System	19 Oct 2020 22:21:48

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-19T18:21:32', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '0f246fa8-a542-443c-b2d4-294c15dc5f75' User entered 'None (0)'	System	19 Oct 2020 22:21:48
	System	19 Oct 2020 22:21:48

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-19T18:21:40', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '0f246fa8-a542-443c-b2d4-294c15dc5f75' User entered 'None (0)'	System	19 Oct 2020 22:21:48
	System	19 Oct 2020 22:21:48

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-19T18:21:43', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '0f246fa8-a542-443c-b2d4-294c15dc5f75'	System	19 Oct 2020 22:21:48
User entered 'No (N)'	System	19 Oct 2020 22:21:48

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-19T18:21:46', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '0f246fa8-a542-443c-b2d4-294c15dc5f75' User entered '19 Oct 2020 18:21'	System	19 Oct 2020 22:21:48
	System	19 Oct 2020 22:21:48

US3632127

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 11:39:14
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

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 11:39:14
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: MuscleAche_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 11:39:14
Data entry locked.	System	18 Oct 2020 22:12:11
User entered 'Day 8'	System	18 Oct 2020 22:12:11

US3632127

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:08:05

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-20T14:19:57', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8781dc80-270f-4334-87a6-304e5c481a1f' User entered 'None (0)'	System	20 Oct 2020 18:20:07
	System	20 Oct 2020 18:20:07

US3632127

Folder: Diary Dose 1 (1)

Form: MuscleAche_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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-20T14:20:03', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8781dc80-270f-4334-87a6-304e5c481a1f' User entered '20 Oct 2020 14:20'	System	20 Oct 2020 18:20:07
	System	20 Oct 2020 18:20:07

US3632127

Folder: Diary Dose 1 (1)

Form: MuscleAche_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 11:39:14
User entered '20 Oct 2020 12:00'	System	18 Oct 2020 22:12:11

US3632127

Folder: Diary Dose 1 (1)

Form: MuscleAche_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 11:39:14
User entered '21 Oct 2020 11:59'	System	18 Oct 2020 22:12:11

US3632127

Folder: Diary Dose 1 (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 11:39:14
Data entry locked.	System	18 Oct 2020 22:12:11
User entered 'Day 8'	System	18 Oct 2020 22:12:11

US3632127

Folder: Diary Dose 1 (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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-20T14:20:09', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '6b34973b-9b8e-499e-8457-c9476778860a'	System	20 Oct 2020 18:20:14
User entered 'No (N)'	System	20 Oct 2020 18:20:14

US3632127

Folder: Diary Dose 1 (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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-20T14:20:13', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '6b34973b-9b8e-499e-8457-c9476778860a' User entered '20 Oct 2020 14:20'	System	20 Oct 2020 18:20:14
	System	20 Oct 2020 18:20:14

US3632127

Folder: Diary Dose 1 (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 11:39:14
User entered '20 Oct 2020 12:00'	System	18 Oct 2020 22:12:11

US3632127

Folder: Diary Dose 1 (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 11:39:14
User entered '21 Oct 2020 11:59'	System	18 Oct 2020 22:12:11

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:11:41
User entered 'Yes (Y)'	Bezuayehu Mandefro (b) (4)	20 Oct 2020 15:12:48

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:11:41
User entered '20 Oct 2020'	Bezuayehu Mandefro (b) (4)	20 Oct 2020 15:12:48

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:11:41
User entered 'Contact Made (CONTACT MADE)'	Bezuayehu Mandefro (b) (4)	20 Oct 2020 15:12:48

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:11:41
User entered empty.	Bezuayehu Mandefro (b) (4)	20 Oct 2020 15:12:48

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:12:16
User entered 'Yes (Y)'	Bezuayehu Mandefro (b) (4)	20 Oct 2020 15:12:53

US3632127

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)	28 Mar 2021 01:33:19
User entered '1'	System	20 Oct 2020 15:12:53

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:12:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 18:00:29

US3632127

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)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:12:59
User entered '27 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 18:00:29

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:12:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	27 Oct 2020 18:00:29

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:12:59
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 18:00:29

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:13:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 18:00:33

US3632127

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)	28 Mar 2021 01:33:19
User entered '1'	System	27 Oct 2020 18:00:33

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:13:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 16:06:11

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:13:55
User entered '3 Nov 2020'	(b) (4), (b) (6)	03 Nov 2020 16:06:11

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:13:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	03 Nov 2020 16:06:11

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:13:55
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 16:06:11

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:14:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 16:06:02

US3632127

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)	28 Mar 2021 01:33:19
User entered '1'	System	03 Nov 2020 16:06:02

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:14:38
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:21:25

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:14:38
User entered '11 Nov 2020'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:21:25

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:14:38
User entered 'Clinic (Clinic)'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:21:25

US3632127

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)	28 Mar 2021 01:33:19
User entered 'VISIT2'	System	11 Nov 2020 14:21:25

US3632127

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)	28 Mar 2021 01:33:19
User accepted default value 'Pre-Dose (PREDOSE)'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:28:40
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:28:40
User entered '11 Nov 2020'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:28:40
User entered '08:15'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

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)	28 Mar 2021 01:33:19
User entered '11 Nov 2020 08:15'	System	11 Nov 2020 16:08:34

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:28:40
User entered '97.9' F	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:28:40
User entered 'Oral (Oral)'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:28:40
User entered empty.	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:28:40
User entered '80'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

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)	28 Mar 2021 01:33:19
User entered 'bpm'	System	11 Nov 2020 16:08:34

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:28:40
User entered '14'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

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)	28 Mar 2021 01:33:19
User entered 'breaths/min'	System	11 Nov 2020 16:08:34

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:28:40
User entered '114'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

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)	28 Mar 2021 01:33:19
User entered 'mmHg'	System	11 Nov 2020 16:08:34

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:28:40
User entered '77'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

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)	28 Mar 2021 01:33:19
User entered 'mmHg'	System	11 Nov 2020 16:08:34

US3632127

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)	28 Mar 2021 01:33:19
User accepted default value 'Post-Dose (POSTDOSE)'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:34:25
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:34:25
User entered '11 Nov 2020'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:34:25
User entered '10:31'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

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)	28 Mar 2021 01:33:19
User entered '11 Nov 2020 10:31'	System	11 Nov 2020 16:08:34

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:34:25
User entered '98.3' F	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:34:25
User entered 'Oral (Oral)'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:34:25
User entered empty.	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:34:25
User entered '79'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

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)	28 Mar 2021 01:33:19
User entered 'bpm'	System	11 Nov 2020 16:08:34

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:34:25
User entered '20'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

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)	28 Mar 2021 01:33:19
User entered 'breaths/min'	System	11 Nov 2020 16:08:34

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:34:25
User entered '110'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

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)	28 Mar 2021 01:33:19
User entered 'mmHg'	System	11 Nov 2020 16:08:34

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:34:25
User entered '68'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

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)	28 Mar 2021 01:33:19
User entered 'mmHg'	System	11 Nov 2020 16:08:34

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:34:37
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:21:33

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:34:37
User entered '11 Nov 2020'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:21:33

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:34:58
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:55:46

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:34:58
User entered empty.	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:55:46

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:34:58
User entered empty.	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:55:46

US3632127

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)	28 Mar 2021 01:33:19
User entered 'MRNA-1273 OR PLACEBO'	System	11 Nov 2020 14:55:46

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:34:58
User entered '11 Nov 2020'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:55:46

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:34:58
User entered '09:51'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:55:46

US3632127

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)	28 Mar 2021 01:33:19
User entered '11 Nov 2020 09:51'	System	11 Nov 2020 14:55:46

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:34:58
User entered 'Left Arm (LEFT ARM)'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:55:46

US3632127

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)	28 Mar 2021 01:33:19
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:34:58
User entered 'ONCE'	System	11 Nov 2020 14:55:46

US3632127

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)	28 Mar 2021 01:33:19
User entered 'INTRAMUSCULAR'	System	11 Nov 2020 14:55:46

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:53
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:21:44

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:53
User entered '11 Nov 2020'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:21:44

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:53
User entered '08:55'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:21:44

US3632127

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)	28 Mar 2021 01:33:19
User entered '11 Nov 2020 08:55'	System	11 Nov 2020 14:21:44

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:59
User entered '11 Nov 2020'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:21:58

US3632127

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)	28 Mar 2021 01:33:19
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:21:58

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:59
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:21:58

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:59
User entered '09:01'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:21:58

US3632127

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)	28 Mar 2021 01:33:19
User entered '11 Nov 2020 09:01'	System	11 Nov 2020 14:21:58

US3632127

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)	28 Mar 2021 01:33:19
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:21:58

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:59
User entered 'No (N)'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:21:58

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:35:59
User entered empty.	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:21:58

US3632127

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)	28 Mar 2021 01:33:19
User entered empty.	System	11 Nov 2020 14:21:58

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:36:09
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:41

US3632127

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)	28 Mar 2021 01:33:19
User entered '1'	System	11 Nov 2020 16:08:41

US3632127

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 11:39:14
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T10:29:35', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ef5619fb-f153-4251-9f2a-ca6b784174e6' User entered 'Yes (Y)'	System	11 Nov 2020 15:29:58
	System	11 Nov 2020 15:29:58

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T10:29:43', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ef5619fb-f153-4251-9f2a-ca6b784174e6' User entered '98.3'	System	11 Nov 2020 15:29:58
	System	11 Nov 2020 15:29:58

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T10:29:47', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ef5619fb-f153-4251-9f2a-ca6b784174e6'	System	11 Nov 2020 15:29:58
User entered 'No (N)'	System	11 Nov 2020 15:29:58

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T10:29:55', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ef5619fb-f153-4251-9f2a-ca6b784174e6' User entered '11 Nov 2020 10:29'	System	11 Nov 2020 15:29:58
	System	11 Nov 2020 15:29:58

US3632127

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 11:39:14
User entered '11 Nov 2020 10:11'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
User entered '11 Nov 2020 12:41'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 1, after vaccination (at home)'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T19:59:40', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '3eb13b19-d5a8-4905-86c3-7de62e136141' User entered 'Yes (Y)'	System	12 Nov 2020 00:59:59
	System	12 Nov 2020 00:59:59

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T19:59:49', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '3eb13b19-d5a8-4905-86c3-7de62e136141' User entered '98.1'	System	12 Nov 2020 00:59:59
	System	12 Nov 2020 00:59:59

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T19:59:52', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '3eb13b19-d5a8-4905-86c3-7de62e136141'	System	12 Nov 2020 00:59:59
User entered 'No (N)'	System	12 Nov 2020 00:59:59

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T19:59:56', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '3eb13b19-d5a8-4905-86c3-7de62e136141' User entered '11 Nov 2020 19:59'	System	12 Nov 2020 00:59:59
	System	12 Nov 2020 00:59:59

US3632127

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 11:39:14
User entered '11 Nov 2020 13:36'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
User entered '12 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 2'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-12T15:04:57', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '59a1e157-9aaf-4107-8bc7-4d04f288a5fa' User entered 'Yes (Y)'	System	12 Nov 2020 20:05:53
	System	12 Nov 2020 20:05:53

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-12T15:05:38', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '59a1e157-9aaf-4107-8bc7-4d04f288a5fa' User entered '98.7'	System	12 Nov 2020 20:05:53
	System	12 Nov 2020 20:05:53

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-12T15:05:42', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '59a1e157-9aaf-4107-8bc7-4d04f288a5fa' User entered 'No (N)'	System	12 Nov 2020 20:05:53
	System	12 Nov 2020 20:05:53

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-12T15:05:48', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '59a1e157-9aaf-4107-8bc7-4d04f288a5fa' User entered '12 Nov 2020 15:05'	System	12 Nov 2020 20:05:53
	System	12 Nov 2020 20:05:53

US3632127

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 11:39:14
User entered '12 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
User entered '13 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 3'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-13T16:04:05', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e77f448b-3a4f-4799-b86c-59bffe53170a' User entered 'Yes (Y)'	System	13 Nov 2020 21:04:30
	System	13 Nov 2020 21:04:30

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-13T16:04:12', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e77f448b-3a4f-4799-b86c-59bffe53170a' User entered '97.6'	System	13 Nov 2020 21:04:30
	System	13 Nov 2020 21:04:30

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-13T16:04:17', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e77f448b-3a4f-4799-b86c-59bffe53170a'	System	13 Nov 2020 21:04:30
User entered 'No (N)'	System	13 Nov 2020 21:04:30

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-13T16:04:25', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e77f448b-3a4f-4799-b86c-59bffe53170a' User entered '13 Nov 2020 16:04'	System	13 Nov 2020 21:04:30
	System	13 Nov 2020 21:04:30

US3632127

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 11:39:14
User entered '13 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
User entered '14 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 4'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-14T13:49:35', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e9c5a72c-9536-4e5f-befd-9eda2376c466'	System	14 Nov 2020 18:50:25
User entered 'Yes (Y)'	System	14 Nov 2020 18:50:25

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-14T13:50:11', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e9c5a72c-9536-4e5f-befd-9eda2376c466'	System	14 Nov 2020 18:50:25
User entered '97.6'	System	14 Nov 2020 18:50:25

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-14T13:50:18', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e9c5a72c-9536-4e5f-befd-9eda2376c466'	System	14 Nov 2020 18:50:25
User entered 'No (N)'	System	14 Nov 2020 18:50:25

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-14T13:50:23', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e9c5a72c-9536-4e5f-befd-9eda2376c466'	System	14 Nov 2020 18:50:25
User entered '14 Nov 2020 13:50'	System	14 Nov 2020 18:50:25

US3632127

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 11:39:14
User entered '14 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
User entered '15 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 5'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-15T14:30:25', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e27330d4-d447-4ce1-aaca-d040aeb0b5b4' User entered 'Yes (Y)'	System	15 Nov 2020 19:30:52
	System	15 Nov 2020 19:30:52

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-15T14:30:33', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e27330d4-d447-4ce1-aaca-d040aeb0b5b4' User entered '98.1'	System	15 Nov 2020 19:30:52
	System	15 Nov 2020 19:30:52

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-15T14:30:36', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e27330d4-d447-4ce1-aaca-d040aeb0b5b4' User entered 'No (N)'	System	15 Nov 2020 19:30:52
	System	15 Nov 2020 19:30:52

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-15T14:30:47', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e27330d4-d447-4ce1-aaca-d040aeb0b5b4' User entered '15 Nov 2020 14:30'	System	15 Nov 2020 19:30:52
	System	15 Nov 2020 19:30:52

US3632127

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 11:39:14
User entered '15 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
User entered '16 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 6'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-16T14:50:46', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a9ec7036-b74d-4469-802d-41dafbaf7e2d' User entered 'Yes (Y)'	System	16 Nov 2020 19:51:53
	System	16 Nov 2020 19:51:53

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-16T14:51:40', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a9ec7036-b74d-4469-802d-41dafbaf7e2d' User entered '98.3'	System	16 Nov 2020 19:51:53
	System	16 Nov 2020 19:51:53

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-16T14:51:44', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a9ec7036-b74d-4469-802d-41dafbaf7e2d'	System	16 Nov 2020 19:51:53
User entered 'No (N)'	System	16 Nov 2020 19:51:53

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-16T14:51:47', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a9ec7036-b74d-4469-802d-41dafbaf7e2d' User entered '16 Nov 2020 14:51'	System	16 Nov 2020 19:51:53
	System	16 Nov 2020 19:51:53

US3632127

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 11:39:14
User entered '16 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
User entered '17 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 7'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-17T12:05:44', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'fbd637a7-3ccb-4802-b905-0f3ef3ffdf52'	System	17 Nov 2020 17:06:00
User entered 'Yes (Y)'	System	17 Nov 2020 17:06:00

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-17T12:05:51', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'fbd637a7-3ccb-4802-b905-0f3ef3ffdf52'	System	17 Nov 2020 17:06:00
User entered '98.1'	System	17 Nov 2020 17:06:00

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-17T12:05:55', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'fbd637a7-3ccb-4802-b905-0f3ef3ffdf52'	System	17 Nov 2020 17:06:00
User entered 'No (N)'	System	17 Nov 2020 17:06:00

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-17T12:05:58', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'fbd637a7-3ccb-4802-b905-0f3ef3ffdf52' User entered '17 Nov 2020 12:05'	System	17 Nov 2020 17:06:00
	System	17 Nov 2020 17:06:00

US3632127

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 11:39:14
User entered '17 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
User entered '18 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T10:30:07', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8fca385e-1047-4666-88da-c477e32c4187'	System	11 Nov 2020 15:30:51
User entered 'None (1)'	System	11 Nov 2020 15:30:51

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T10:30:20', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8fca385e-1047-4666-88da-c477e32c4187'	System	11 Nov 2020 15:30:51
User entered 'No (N)'	System	11 Nov 2020 15:30:51

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T10:30:30', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8fca385e-1047-4666-88da-c477e32c4187'	System	11 Nov 2020 15:30:51
User entered 'No (N)'	System	11 Nov 2020 15:30:51

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T10:30:45', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8fca385e-1047-4666-88da-c477e32c4187'	System	11 Nov 2020 15:30:51
User entered 'None (1)'	System	11 Nov 2020 15:30:51

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T10:30:49', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8fca385e-1047-4666-88da-c477e32c4187' User entered '11 Nov 2020 10:30'	System	11 Nov 2020 15:30:51
	System	11 Nov 2020 15:30:51

US3632127

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 11:39:14
User entered '11 Nov 2020 10:11'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
User entered '11 Nov 2020 12:41'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 1, after vaccination (at home)'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T20:00:01', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'c86f19f7-a542-4d69-9481-d6dd36901cf1'	System	12 Nov 2020 01:00:15
User entered 'None (1)'	System	12 Nov 2020 01:00:15

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T20:00:05', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'c86f19f7-a542-4d69-9481-d6dd36901cf1' User entered 'No (N)'	System	12 Nov 2020 01:00:15
	System	12 Nov 2020 01:00:15

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T20:00:08', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'c86f19f7-a542-4d69-9481-d6dd36901cf1' User entered 'No (N)'	System	12 Nov 2020 01:00:15
	System	12 Nov 2020 01:00:15

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T20:00:10', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'c86f19f7-a542-4d69-9481-d6dd36901cf1' User entered 'None (1)'	System	12 Nov 2020 01:00:15
	System	12 Nov 2020 01:00:15

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T20:00:14', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'c86f19f7-a542-4d69-9481-d6dd36901cf1' User entered '11 Nov 2020 20:00'	System	12 Nov 2020 01:00:15
	System	12 Nov 2020 01:00:15

US3632127

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 11:39:14
User entered '11 Nov 2020 13:36'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
User entered '12 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 2'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-12T15:06:17', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7b93190e-e333-4e98-9031-ce4fcb738481'	System	12 Nov 2020 20:08:10
User entered 'None (1)'	System	12 Nov 2020 20:08:10

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-12T15:07:36', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7b93190e-e333-4e98-9031-ce4fcb738481' User entered 'No (N)'	System	12 Nov 2020 20:08:10
	System	12 Nov 2020 20:08:10

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-12T15:07:59', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7b93190e-e333-4e98-9031-ce4fcb738481' User entered 'No (N)'	System	12 Nov 2020 20:08:10
	System	12 Nov 2020 20:08:10

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-12T15:08:02', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7b93190e-e333-4e98-9031-ce4fcb738481' User entered 'None (1)'	System	12 Nov 2020 20:08:10
	System	12 Nov 2020 20:08:10

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-12T15:08:06', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7b93190e-e333-4e98-9031-ce4fcb738481' User entered '12 Nov 2020 15:08'	System	12 Nov 2020 20:08:10
	System	12 Nov 2020 20:08:10

US3632127

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 11:39:14
User entered '12 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
User entered '13 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 3'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-13T16:04:35', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '9c2304e3-0a79-47b9-9cda-2bce4426e821'	System	13 Nov 2020 21:05:45
User entered 'None (1)'	System	13 Nov 2020 21:05:45

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-13T16:04:40', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '9c2304e3-0a79-47b9-9cda-2bce4426e821'	System	13 Nov 2020 21:05:45
User entered 'No (N)'	System	13 Nov 2020 21:05:45

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-13T16:04:44', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '9c2304e3-0a79-47b9-9cda-2bce4426e821'	System	13 Nov 2020 21:05:45
User entered 'No (N)'	System	13 Nov 2020 21:05:45

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-13T16:04:49', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '9c2304e3-0a79-47b9-9cda-2bce4426e821' User entered 'None (1)'	System	13 Nov 2020 21:05:45
	System	13 Nov 2020 21:05:45

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-13T16:04:52', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '9c2304e3-0a79-47b9-9cda-2bce4426e821' User entered '13 Nov 2020 16:04'	System	13 Nov 2020 21:05:45
	System	13 Nov 2020 21:05:45

US3632127

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 11:39:14
User entered '13 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
User entered '14 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 4'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-14T13:50:47', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '1c6df213-fcfa-43c3-9117-0b3a831bf3d4'	System	14 Nov 2020 18:51:22
User entered 'None (1)'	System	14 Nov 2020 18:51:22

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-14T13:50:52', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '1c6df213-fcfa-43c3-9117-0b3a831bf3d4'	System	14 Nov 2020 18:51:22
User entered 'No (N)'	System	14 Nov 2020 18:51:22

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-14T13:51:01', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '1c6df213-fcfa-43c3-9117-0b3a831bf3d4'	System	14 Nov 2020 18:51:22
User entered 'No (N)'	System	14 Nov 2020 18:51:22

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-14T13:51:14', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '1c6df213-fcfa-43c3-9117-0b3a831bf3d4'	System	14 Nov 2020 18:51:22
User entered 'None (1)'	System	14 Nov 2020 18:51:22

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-14T13:51:19', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '1c6df213-fcfa-43c3-9117-0b3a831bf3d4' User entered '14 Nov 2020 13:51'	System	14 Nov 2020 18:51:22
	System	14 Nov 2020 18:51:22

US3632127

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 11:39:14
User entered '14 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
User entered '15 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 5'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-15T14:31:02', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a961f60f-ae08-4a1e-af4a-65bb212c18be'	System	15 Nov 2020 19:31:27
User entered 'None (1)'	System	15 Nov 2020 19:31:27

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-15T14:31:06', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a961f60f-ae08-4a1e-af4a-65bb212c18be' User entered 'No (N)'	System	15 Nov 2020 19:31:27
	System	15 Nov 2020 19:31:27

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-15T14:31:11', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a961f60f-ae08-4a1e-af4a-65bb212c18be' User entered 'No (N)'	System	15 Nov 2020 19:31:27
	System	15 Nov 2020 19:31:27

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-15T14:31:17', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a961f60f-ae08-4a1e-af4a-65bb212c18be'	System	15 Nov 2020 19:31:27
User entered 'None (1)'	System	15 Nov 2020 19:31:27

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-15T14:31:23', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a961f60f-ae08-4a1e-af4a-65bb212c18be' User entered '15 Nov 2020 14:31'	System	15 Nov 2020 19:31:27
	System	15 Nov 2020 19:31:27

US3632127

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 11:39:14
User entered '15 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
User entered '16 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 6'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-16T14:51:53', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '0e975e5f-8783-4b04-8af3-591fe2cd9459'	System	16 Nov 2020 19:52:16
User entered 'None (1)'	System	16 Nov 2020 19:52:16

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-16T14:51:58', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '0e975e5f-8783-4b04-8af3-591fe2cd9459'	System	16 Nov 2020 19:52:16
User entered 'No (N)'	System	16 Nov 2020 19:52:16

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-16T14:52:03', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '0e975e5f-8783-4b04-8af3-591fe2cd9459' User entered 'No (N)'	System	16 Nov 2020 19:52:16
	System	16 Nov 2020 19:52:16

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-16T14:52:07', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '0e975e5f-8783-4b04-8af3-591fe2cd9459'	System	16 Nov 2020 19:52:16
User entered 'None (1)'	System	16 Nov 2020 19:52:16

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-16T14:52:09', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '0e975e5f-8783-4b04-8af3-591fe2cd9459' User entered '16 Nov 2020 14:52'	System	16 Nov 2020 19:52:16
	System	16 Nov 2020 19:52:16

US3632127

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 11:39:14
User entered '16 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
User entered '17 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 7'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-17T12:06:07', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7da78623-593a-4450-90c6-477cd6006492'	System	17 Nov 2020 17:06:24
User entered 'None (1)'	System	17 Nov 2020 17:06:24

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-17T12:06:10', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7da78623-593a-4450-90c6-477cd6006492'	System	17 Nov 2020 17:06:24
User entered 'No (N)'	System	17 Nov 2020 17:06:24

US3632127

Folder: Diary Dose 2 (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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-17T12:06:14', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7da78623-593a-4450-90c6-477cd6006492'	System	17 Nov 2020 17:06:24
User entered 'No (N)'	System	17 Nov 2020 17:06:24

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-17T12:06:18', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7da78623-593a-4450-90c6-477cd6006492'	System	17 Nov 2020 17:06:24
User entered 'None (1)'	System	17 Nov 2020 17:06:24

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-17T12:06:21', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7da78623-593a-4450-90c6-477cd6006492'	System	17 Nov 2020 17:06:24
User entered '17 Nov 2020 12:06'	System	17 Nov 2020 17:06:24

US3632127

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 11:39:14
User entered '17 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
User entered '18 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T10:30:55', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '774a3f3c-0399-4013-b7b5-4925a76b34c7' User entered 'None (0)'	System	11 Nov 2020 15:31:26
	System	11 Nov 2020 15:31:26

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T10:30:59', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '774a3f3c-0399-4013-b7b5-4925a76b34c7' User entered 'None (0)'	System	11 Nov 2020 15:31:26
	System	11 Nov 2020 15:31:26

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T10:31:02', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '774a3f3c-0399-4013-b7b5-4925a76b34c7' User entered 'None (0)'	System	11 Nov 2020 15:31:26
	System	11 Nov 2020 15:31:26

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T10:31:05', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '774a3f3c-0399-4013-b7b5-4925a76b34c7' User entered 'None (0)'	System	11 Nov 2020 15:31:26
	System	11 Nov 2020 15:31:26

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T10:31:08', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '774a3f3c-0399-4013-b7b5-4925a76b34c7' User entered 'None (0)'	System	11 Nov 2020 15:31:26
	System	11 Nov 2020 15:31:26

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T10:31:12', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '774a3f3c-0399-4013-b7b5-4925a76b34c7' User entered 'None (0)'	System	11 Nov 2020 15:31:26
	System	11 Nov 2020 15:31:26

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T10:31:17', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '774a3f3c-0399-4013-b7b5-4925a76b34c7' User entered 'No (N)'	System	11 Nov 2020 15:31:26
	System	11 Nov 2020 15:31:26

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T10:31:24', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '774a3f3c-0399-4013-b7b5-4925a76b34c7' User entered '11 Nov 2020 10:31'	System	11 Nov 2020 15:31:26
	System	11 Nov 2020 15:31:26

US3632127

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 11:39:14
User entered '11 Nov 2020 10:11'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
User entered '11 Nov 2020 12:41'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 1, after vaccination (at home)'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T20:00:19', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'da3123f2-a1bf-48a9-a1f5-9ec521bac54b' User entered 'None (0)'	System	12 Nov 2020 01:00:51
	System	12 Nov 2020 01:00:51

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T20:00:22', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'da3123f2-a1bf-48a9-a1f5-9ec521bac54b' User entered 'None (0)'	System	12 Nov 2020 01:00:51
	System	12 Nov 2020 01:00:51

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T20:00:25', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'da3123f2-a1bf-48a9-a1f5-9ec521bac54b'	System	12 Nov 2020 01:00:51
User entered 'No interference with activity (1)'	System	12 Nov 2020 01:00:51

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T20:00:28', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'da3123f2-a1bf-48a9-a1f5-9ec521bac54b'	System	12 Nov 2020 01:00:51
User entered 'No interference with activity (1)'	System	12 Nov 2020 01:00:51

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T20:00:34', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'da3123f2-a1bf-48a9-a1f5-9ec521bac54b'	System	12 Nov 2020 01:00:51
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	12 Nov 2020 01:00:51

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T20:00:36', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'da3123f2-a1bf-48a9-a1f5-9ec521bac54b' User entered 'None (0)'	System	12 Nov 2020 01:00:51
	System	12 Nov 2020 01:00:51

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T20:00:41', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'da3123f2-a1bf-48a9-a1f5-9ec521bac54b' User entered 'No (N)'	System	12 Nov 2020 01:00:51
	System	12 Nov 2020 01:00:51

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T20:00:43', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'da3123f2-a1bf-48a9-a1f5-9ec521bac54b' User entered '11 Nov 2020 20:00'	System	12 Nov 2020 01:00:51
	System	12 Nov 2020 01:00:51

US3632127

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 11:39:14
User entered '11 Nov 2020 13:36'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
User entered '12 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 2'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-12T15:08:13', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '32d6e9e0-6c22-4f50-a721-00b0c86faaa4' User entered 'None (0)'	System	12 Nov 2020 20:09:40
	System	12 Nov 2020 20:09:40

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-12T15:08:35', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '32d6e9e0-6c22-4f50-a721-00b0c86faaa4' User entered 'None (0)'	System	12 Nov 2020 20:09:40
	System	12 Nov 2020 20:09:40

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-12T15:08:42', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '32d6e9e0-6c22-4f50-a721-00b0c86faaa4'	System	12 Nov 2020 20:09:40
User entered 'None (0)'	System	12 Nov 2020 20:09:40

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-12T15:08:45', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '32d6e9e0-6c22-4f50-a721-00b0c86faaa4' User entered 'None (0)'	System	12 Nov 2020 20:09:40
	System	12 Nov 2020 20:09:40

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-12T15:08:51', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '32d6e9e0-6c22-4f50-a721-00b0c86faaa4'	System	12 Nov 2020 20:09:40
User entered 'None (0)'	System	12 Nov 2020 20:09:40

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-12T15:09:16', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '32d6e9e0-6c22-4f50-a721-00b0c86faaa4' User entered 'None (0)'	System	12 Nov 2020 20:09:40
	System	12 Nov 2020 20:09:40

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-12T15:09:33', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '32d6e9e0-6c22-4f50-a721-00b0c86faaa4'	System	12 Nov 2020 20:09:40
User entered 'No (N)'	System	12 Nov 2020 20:09:40

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-12T15:09:36', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '32d6e9e0-6c22-4f50-a721-00b0c86faaa4' User entered '12 Nov 2020 15:09'	System	12 Nov 2020 20:09:40
	System	12 Nov 2020 20:09:40

US3632127

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 11:39:14
User entered '12 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
User entered '13 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 3'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-13T16:04:59', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'aea84a8f-9991-49d3-86a1-92e01b9400b0' User entered 'None (0)'	System	13 Nov 2020 21:06:01
	System	13 Nov 2020 21:06:01

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-13T16:05:05', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'aea84a8f-9991-49d3-86a1-92e01b9400b0' User entered 'None (0)'	System	13 Nov 2020 21:06:01
	System	13 Nov 2020 21:06:01

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-13T16:05:12', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'aea84a8f-9991-49d3-86a1-92e01b9400b0'	System	13 Nov 2020 21:06:01
User entered 'No interference with activity (1)'	System	13 Nov 2020 21:06:01

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-13T16:05:16', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'aea84a8f-9991-49d3-86a1-92e01b9400b0' User entered 'No interference with activity (1)'	System	13 Nov 2020 21:06:01
	System	13 Nov 2020 21:06:01

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-13T16:05:19', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'aea84a8f-9991-49d3-86a1-92e01b9400b0' User entered 'None (0)'	System	13 Nov 2020 21:06:01
	System	13 Nov 2020 21:06:01

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-13T16:05:22', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'aea84a8f-9991-49d3-86a1-92e01b9400b0' User entered 'None (0)'	System	13 Nov 2020 21:06:01
	System	13 Nov 2020 21:06:01

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-13T16:05:31', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'aea84a8f-9991-49d3-86a1-92e01b9400b0' User entered 'No (N)'	System	13 Nov 2020 21:06:01
	System	13 Nov 2020 21:06:01

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-13T16:05:34', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'aea84a8f-9991-49d3-86a1-92e01b9400b0' User entered '13 Nov 2020 16:05'	System	13 Nov 2020 21:06:01
	System	13 Nov 2020 21:06:01

US3632127

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 11:39:14
User entered '13 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
User entered '14 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 4'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-14T13:51:26', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '07bf9ba7-cde7-4683-ba1c-910fe12176fc' User entered 'None (0)'	System	14 Nov 2020 18:51:59
	System	14 Nov 2020 18:51:59

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-14T13:51:30', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '07bf9ba7-cde7-4683-ba1c-910fe12176fc' User entered 'None (0)'	System	14 Nov 2020 18:51:59
	System	14 Nov 2020 18:51:59

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-14T13:51:34', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '07bf9ba7-cde7-4683-ba1c-910fe12176fc' User entered 'None (0)'	System	14 Nov 2020 18:51:59
	System	14 Nov 2020 18:51:59

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-14T13:51:39', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '07bf9ba7-cde7-4683-ba1c-910fe12176fc' User entered 'None (0)'	System	14 Nov 2020 18:51:59
	System	14 Nov 2020 18:51:59

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-14T13:51:42', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '07bf9ba7-cde7-4683-ba1c-910fe12176fc' User entered 'None (0)'	System	14 Nov 2020 18:51:59
	System	14 Nov 2020 18:51:59

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-14T13:51:46', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '07bf9ba7-cde7-4683-ba1c-910fe12176fc' User entered 'None (0)'	System	14 Nov 2020 18:51:59
	System	14 Nov 2020 18:51:59

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-14T13:51:52', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '07bf9ba7-cde7-4683-ba1c-910fe12176fc' User entered 'No (N)'	System	14 Nov 2020 18:51:59
	System	14 Nov 2020 18:51:59

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-14T13:51:55', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '07bf9ba7-cde7-4683-ba1c-910fe12176fc' User entered '14 Nov 2020 13:51'	System	14 Nov 2020 18:51:59
	System	14 Nov 2020 18:51:59

US3632127

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 11:39:14
User entered '14 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
User entered '15 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 5'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-15T14:31:32', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'b7ba0cca-fefd-4ef7-b27f-0eb7a84a2c07' User entered 'None (0)'	System	15 Nov 2020 19:32:29
	System	15 Nov 2020 19:32:29

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-15T14:31:36', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'b7ba0cca-fefd-4ef7-b27f-0eb7a84a2c07'	System	15 Nov 2020 19:32:29
User entered 'No interference with activity (1)'	System	15 Nov 2020 19:32:29

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-15T14:31:41', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'b7ba0cca-fefd-4ef7-b27f-0eb7a84a2c07'	System	15 Nov 2020 19:32:29
User entered 'No interference with activity (1)'	System	15 Nov 2020 19:32:29

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-15T14:31:53', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'b7ba0cca-fefd-4ef7-b27f-0eb7a84a2c07'	System	15 Nov 2020 19:32:29
User entered 'No interference with activity (1)'	System	15 Nov 2020 19:32:29

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-15T14:31:57', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'b7ba0cca-fefd-4ef7-b27f-0eb7a84a2c07' User entered 'None (0)'	System	15 Nov 2020 19:32:29
	System	15 Nov 2020 19:32:29

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-15T14:32:04', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'b7ba0cca-fefd-4ef7-b27f-0eb7a84a2c07' User entered 'None (0)'	System	15 Nov 2020 19:32:29
	System	15 Nov 2020 19:32:29

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-15T14:32:20', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'b7ba0cca-fefd-4ef7-b27f-0eb7a84a2c07'	System	15 Nov 2020 19:32:29
User entered 'No (N)'	System	15 Nov 2020 19:32:29

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-15T14:32:25', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'b7ba0cca-fefd-4ef7-b27f-0eb7a84a2c07' User entered '15 Nov 2020 14:32'	System	15 Nov 2020 19:32:29
	System	15 Nov 2020 19:32:29

US3632127

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 11:39:14
User entered '15 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
User entered '16 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 6'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-16T14:52:15', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ac2d8c76-57c9-481c-8c9c-044990f4610f' User entered 'None (0)'	System	16 Nov 2020 19:52:44
	System	16 Nov 2020 19:52:44

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-16T14:52:19', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ac2d8c76-57c9-481c-8c9c-044990f4610f' User entered 'None (0)'	System	16 Nov 2020 19:52:44
	System	16 Nov 2020 19:52:44

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-16T14:52:22', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ac2d8c76-57c9-481c-8c9c-044990f4610f' User entered 'None (0)'	System	16 Nov 2020 19:52:44
	System	16 Nov 2020 19:52:44

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-16T14:52:26', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ac2d8c76-57c9-481c-8c9c-044990f4610f' User entered 'None (0)'	System	16 Nov 2020 19:52:44
	System	16 Nov 2020 19:52:44

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-16T14:52:30', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ac2d8c76-57c9-481c-8c9c-044990f4610f' User entered 'None (0)'	System	16 Nov 2020 19:52:44
	System	16 Nov 2020 19:52:44

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-16T14:52:32', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ac2d8c76-57c9-481c-8c9c-044990f4610f' User entered 'None (0)'	System	16 Nov 2020 19:52:44
	System	16 Nov 2020 19:52:44

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-16T14:52:35', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ac2d8c76-57c9-481c-8c9c-044990f4610f' User entered 'No (N)'	System	16 Nov 2020 19:52:44
	System	16 Nov 2020 19:52:44

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-16T14:52:39', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ac2d8c76-57c9-481c-8c9c-044990f4610f' User entered '16 Nov 2020 14:52'	System	16 Nov 2020 19:52:44
	System	16 Nov 2020 19:52:44

US3632127

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 11:39:14
User entered '16 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
User entered '17 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 7'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-17T12:06:27', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'c594f089-3a05-4fd8-9835-6c54f506e2c5' User entered 'None (0)'	System	17 Nov 2020 17:06:51
	System	17 Nov 2020 17:06:51

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-17T12:06:30', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'c594f089-3a05-4fd8-9835-6c54f506e2c5' User entered 'None (0)'	System	17 Nov 2020 17:06:51
	System	17 Nov 2020 17:06:51

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-17T12:06:33', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'c594f089-3a05-4fd8-9835-6c54f506e2c5' User entered 'None (0)'	System	17 Nov 2020 17:06:51
	System	17 Nov 2020 17:06:51

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-17T12:06:36', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'c594f089-3a05-4fd8-9835-6c54f506e2c5' User entered 'None (0)'	System	17 Nov 2020 17:06:51
	System	17 Nov 2020 17:06:51

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-17T12:06:39', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'c594f089-3a05-4fd8-9835-6c54f506e2c5' User entered 'None (0)'	System	17 Nov 2020 17:06:51
	System	17 Nov 2020 17:06:51

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-17T12:06:42', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'c594f089-3a05-4fd8-9835-6c54f506e2c5' User entered 'None (0)'	System	17 Nov 2020 17:06:51
	System	17 Nov 2020 17:06:51

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-17T12:06:46', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'c594f089-3a05-4fd8-9835-6c54f506e2c5' User entered 'No (N)'	System	17 Nov 2020 17:06:51
	System	17 Nov 2020 17:06:51

US3632127

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 11:39:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-17T12:06:49', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'c594f089-3a05-4fd8-9835-6c54f506e2c5' User entered '17 Nov 2020 12:06'	System	17 Nov 2020 17:06:51
	System	17 Nov 2020 17:06:51

US3632127

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 11:39:14
User entered '17 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

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 11:39:14
User entered '18 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:37:13
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4) (b) (4)	18 Nov 2020 16:46:49

US3632127

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)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:21
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:37:13
User entered '18 Nov 2020'	Sarah Wiatrek (b) (4)	18 Nov 2020 16:46:49

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:21
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:37:13
User entered 'Contact Made (CONTACT MADE)'	Sarah Wiatrek (b) (4)	18 Nov 2020 16:46:49

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:37:13
User entered empty.	Sarah Wiatrek (b) (4) (b) (4)	18 Nov 2020 16:46:49

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:37:19
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4) (b) (4)	18 Nov 2020 16:46:53

US3632127

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)	28 Mar 2021 01:33:19
User entered '1'	System	18 Nov 2020 16:46:53

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:37:50
User entered 'Yes (Y)'	Isaac Perez (b) (4) (b) (4)	06 Jan 2021 21:43:45

US3632127

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)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:21
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:37:50
User entered '25 Nov 2020'	Isaac Perez (b) (4)	06 Jan 2021 21:43:45

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:21
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:37:50
User entered 'Contact Made (CONTACT MADE)'	Isaac Perez (b) (4)	06 Jan 2021 21:43:45

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:37:50
User entered empty.	Isaac Perez (b) (4) (b) (4)	06 Jan 2021 21:43:45

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:38:16
User entered 'Yes (Y)'	Isaac Perez (b) (4) (b) (4)	06 Jan 2021 21:43:51

US3632127

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)	28 Mar 2021 01:33:19
User entered '1'	System	06 Jan 2021 21:43:51

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:40:10
User entered 'Yes (Y)'	Isaac Perez (b) (4) (b) (4)	07 Jan 2021 13:51:45

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:40:10
User entered '3 Dec 2020'	Isaac Perez (b) (4) (b) (4)	07 Jan 2021 13:51:45

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:40:10
User entered 'Contact Made (CONTACT MADE)'	Isaac Perez (b) (4)	07 Jan 2021 13:51:45

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:40:10
User entered empty.	Isaac Perez (b) (4) (b) (4)	07 Jan 2021 13:51:45

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:21
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:40:18
User entered 'Yes (Y)'	Isaac Perez (b) (4)	07 Jan 2021 13:51:55

US3632127

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)	28 Mar 2021 01:33:19
User entered '1'	System	07 Jan 2021 13:51:55

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:40:26
User entered 'No (N)'	Isaac Perez (b) (4) (b) (4)	07 Jan 2021 13:52:04

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:40:26
User entered empty.	Isaac Perez (b) (4) (b) (4)	07 Jan 2021 13:52:04

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:40:26
User entered empty.	Isaac Perez (b) (4) (b) (4)	07 Jan 2021 13:52:04

US3632127

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)	28 Mar 2021 01:33:19
User entered 'VISIT3'	System	07 Jan 2021 13:52:04

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:40:33
User entered 'No (N)'	Isaac Perez (b) (4) (b) (4)	07 Jan 2021 13:52:13

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:40:33
User entered empty.	Isaac Perez (b) (4) (b) (4)	07 Jan 2021 13:52:13

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:40:33
User entered empty.	Isaac Perez (b) (4) (b) (4)	07 Jan 2021 13:52:13

US3632127

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)	28 Mar 2021 01:33:19
User entered empty.	System	07 Jan 2021 13:52:13

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:40:33
User entered empty.	Isaac Perez (b) (4) (b) (4)	07 Jan 2021 13:52:13

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:40:33
User entered empty.	Isaac Perez (b) (4) (b) (4)	07 Jan 2021 13:52:13

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:40:33
User entered empty.	Isaac Perez (b) (4) (b) (4)	07 Jan 2021 13:52:13

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:40:33
User entered empty.	Isaac Perez (b) (4) (b) (4)	07 Jan 2021 13:52:13

US3632127

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)	28 Mar 2021 01:33:19
User entered empty.	System	07 Jan 2021 13:52:13

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:40:33
User entered empty.	Isaac Perez (b) (4) (b) (4)	07 Jan 2021 13:52:13

US3632127

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)	28 Mar 2021 01:33:19
User entered empty.	System	07 Jan 2021 13:52:13

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:40:33
User entered empty.	Isaac Perez (b) (4) (b) (4)	07 Jan 2021 13:52:13

US3632127

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)	28 Mar 2021 01:33:19
User entered empty.	System	07 Jan 2021 13:52:13

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:40:33
User entered empty.	Isaac Perez (b) (4) (b) (4)	07 Jan 2021 13:52:13

US3632127

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)	28 Mar 2021 01:33:19
User entered empty.	System	07 Jan 2021 13:52:13

US3632127

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)	28 Mar 2021 01:33:19

US3632127

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)	28 Mar 2021 01:33:19

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:40:43
User entered 'No (N)'	Isaac Perez (b) (4) (b) (4)	07 Jan 2021 13:52:19

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:40:43
User entered empty.	Isaac Perez (b) (4) (b) (4)	07 Jan 2021 13:52:19

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:40:51
User entered 'No (N)'	Isaac Perez (b) (4) (b) (4)	07 Jan 2021 13:52:25

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:40:51
User entered empty.	Isaac Perez (b) (4) (b) (4)	07 Jan 2021 13:52:25

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:40:51
User entered empty.	Isaac Perez (b) (4) (b) (4)	07 Jan 2021 13:52:25

US3632127

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)	28 Mar 2021 01:33:19
User entered empty.	System	07 Jan 2021 13:52:25

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:40:58
User entered 'Yes (Y)'	Isaac Perez (b) (4) (b) (4)	07 Jan 2021 13:52:31

US3632127

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)	28 Mar 2021 01:33:19
User entered '1'	System	07 Jan 2021 13:52:31

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 12:26:41

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-12-11T08:44:22', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '1cfc339d-65d2-436e-a5b3-13a30b402dd1'	System	11 Dec 2020 13:46:18
User entered 'Yes (Y)'	System	11 Dec 2020 13:46:18

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-12-11T08:44:31', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '1cfc339d-65d2-436e-a5b3-13a30b402dd1' User entered 'No (N)'	System	11 Dec 2020 13:46:18
	System	11 Dec 2020 13:46:18

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-12-11T08:44:43', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '1cfc339d-65d2-436e-a5b3-13a30b402dd1'	System	11 Dec 2020 13:46:18
User entered 'Yes (Y)'	System	11 Dec 2020 13:46:18

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-12-11T08:45:06', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '1cfc339d-65d2-436e-a5b3-13a30b402dd1' User entered '0'	System	11 Dec 2020 13:46:18
	System	11 Dec 2020 13:46:18

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-12-11T08:45:06', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '1cfc339d-65d2-436e-a5b3-13a30b402dd1' User entered '0'	System	11 Dec 2020 13:46:18
	System	11 Dec 2020 13:46:18

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-12-11T08:45:06', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '1cfc339d-65d2-436e-a5b3-13a30b402dd1'	System	11 Dec 2020 13:46:18
User entered '1'	System	11 Dec 2020 13:46:18

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-12-11T08:45:06', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '1cfc339d-65d2-436e-a5b3-13a30b402dd1' User entered '0'	System	11 Dec 2020 13:46:18
	System	11 Dec 2020 13:46:18

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-12-11T08:45:06', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '1cfc339d-65d2-436e-a5b3-13a30b402dd1' User entered '0'	System	11 Dec 2020 13:46:18
	System	11 Dec 2020 13:46:18

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-12-11T08:45:06', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '1cfc339d-65d2-436e-a5b3-13a30b402dd1' User entered '0'	System	11 Dec 2020 13:46:18
	System	11 Dec 2020 13:46:18

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-12-11T08:45:06', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '1cfc339d-65d2-436e-a5b3-13a30b402dd1'	System	11 Dec 2020 13:46:18
User entered '1'	System	11 Dec 2020 13:46:18

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-12-11T08:45:06', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '1cfc339d-65d2-436e-a5b3-13a30b402dd1' User entered '0'	System	11 Dec 2020 13:46:18
	System	11 Dec 2020 13:46:18

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-12-11T08:45:06', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '1cfc339d-65d2-436e-a5b3-13a30b402dd1'	System	11 Dec 2020 13:46:18
User entered '0'	System	11 Dec 2020 13:46:18

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-12-11T08:45:06', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '1cfc339d-65d2-436e-a5b3-13a30b402dd1' User entered '0'	System	11 Dec 2020 13:46:18
	System	11 Dec 2020 13:46:18

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-12-11T08:45:06', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '1cfc339d-65d2-436e-a5b3-13a30b402dd1' User entered '0'	System	11 Dec 2020 13:46:18
	System	11 Dec 2020 13:46:18

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-12-11T08:45:06', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '1cfc339d-65d2-436e-a5b3-13a30b402dd1' User entered '0'	System	11 Dec 2020 13:46:18
	System	11 Dec 2020 13:46:18

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-12-11T08:45:06', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '1cfc339d-65d2-436e-a5b3-13a30b402dd1' User entered '0'	System	11 Dec 2020 13:46:18
	System	11 Dec 2020 13:46:18

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-12-11T08:45:06', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '1cfc339d-65d2-436e-a5b3-13a30b402dd1' User entered '0'	System	11 Dec 2020 13:46:18
	System	11 Dec 2020 13:46:18

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-12-11T08:45:06', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '1cfc339d-65d2-436e-a5b3-13a30b402dd1' User entered '0'	System	11 Dec 2020 13:46:18
	System	11 Dec 2020 13:46:18

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-12-11T08:45:06', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '1cfc339d-65d2-436e-a5b3-13a30b402dd1' User entered '0'	System	11 Dec 2020 13:46:18
	System	11 Dec 2020 13:46:18

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-12-11T08:45:06', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '1cfc339d-65d2-436e-a5b3-13a30b402dd1'	System	11 Dec 2020 13:46:18
User entered '0'	System	11 Dec 2020 13:46:18

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-12-11T08:45:15', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '1cfc339d-65d2-436e-a5b3-13a30b402dd1'	System	11 Dec 2020 13:46:18
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Dec 2020 13:46:18

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-12-11T08:45:27', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '1cfc339d-65d2-436e-a5b3-13a30b402dd1'	System	11 Dec 2020 13:46:18
User entered 'Yes (Y)'	System	11 Dec 2020 13:46:18

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-12-11T08:45:34', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '1cfc339d-65d2-436e-a5b3-13a30b402dd1'	System	11 Dec 2020 13:46:18
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Dec 2020 13:46:18

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-12-11T08:46:09', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '1cfc339d-65d2-436e-a5b3-13a30b402dd1' User entered '11 Dec 2020 08:46:09'	System	11 Dec 2020 13:46:18
	System	11 Dec 2020 13:46:18

US3632127

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 12:26:41
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 12:26:41

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-12-21T21:13:24', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'db7831ea-f0bc-465d-a632-96e3d4deb202'	System	22 Dec 2020 02:13:37
User entered 'No (N)'	System	22 Dec 2020 02:13:37

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-12-21T21:13:29', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'db7831ea-f0bc-465d-a632-96e3d4deb202'	System	22 Dec 2020 02:13:37
User entered 'No (N)'	System	22 Dec 2020 02:13:37

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-12-21T21:13:34', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'db7831ea-f0bc-465d-a632-96e3d4deb202'	System	22 Dec 2020 02:13:37
User entered '21 Dec 2020 21:13:34'	System	22 Dec 2020 02:13:37

US3632127

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 12:26:41
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 12:26:41

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-01-02T20:28:25', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '218754a1-72fe-4ebd-8036-4b208c60fd9c'	System	03 Jan 2021 01:28:40
User entered 'No (N)'	System	03 Jan 2021 01:28:40

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-01-02T20:28:30', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '218754a1-72fe-4ebd-8036-4b208c60fd9c'	System	03 Jan 2021 01:28:40
User entered 'No (N)'	System	03 Jan 2021 01:28:40

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-01-02T20:28:38', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '218754a1-72fe-4ebd-8036-4b208c60fd9c'	System	03 Jan 2021 01:28:40
User entered '02 Jan 2021 20:28:38'	System	03 Jan 2021 01:28:40

US3632127

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 12:26:41
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 12:26:41

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-01-07T14:39:34', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '253050c7-5a87-440b-bdaf-792d63f21457'	System	07 Jan 2021 19:39:47
User entered 'No (N)'	System	07 Jan 2021 19:39:47

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-01-07T14:39:38', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '253050c7-5a87-440b-bdaf-792d63f21457'	System	07 Jan 2021 19:39:47
User entered 'No (N)'	System	07 Jan 2021 19:39:47

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-01-07T14:39:44', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '253050c7-5a87-440b-bdaf-792d63f21457'	System	07 Jan 2021 19:39:47
User entered '07 Jan 2021 14:39:44'	System	07 Jan 2021 19:39:47

US3632127

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 12:26:41
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 12:26:41

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-01-18T11:17:38', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '872c261e-5bc0-4a38-bdf4-21437fda18a4'	System	18 Jan 2021 16:17:59
User entered 'No (N)'	System	18 Jan 2021 16:17:59

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-01-18T11:17:46', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '872c261e-5bc0-4a38-bdf4-21437fda18a4'	System	18 Jan 2021 16:17:59
User entered 'No (N)'	System	18 Jan 2021 16:17:59

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-01-18T11:17:57', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '872c261e-5bc0-4a38-bdf4-21437fda18a4'	System	18 Jan 2021 16:17:59
User entered '18 Jan 2021 11:17:57'	System	18 Jan 2021 16:17:59

US3632127

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 12:26:41
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 12:26:41

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-01-22T15:37:40', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '2742d34a-d9d9-4906-a7db-372abf96eddb' User entered 'No (N)'	System	22 Jan 2021 20:37:54
	System	22 Jan 2021 20:37:54

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-01-22T15:37:44', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '2742d34a-d9d9-4906-a7db-372abf96eddb' User entered 'No (N)'	System	22 Jan 2021 20:37:54

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-01-22T15:37:52', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '2742d34a-d9d9-4906-a7db-372abf96eddb' User entered '22 Jan 2021 15:37:52'	System	22 Jan 2021 20:37:54
	System	22 Jan 2021 20:37:54

US3632127

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 12:26:41
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 12:26:41

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-02-01T16:34:17', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '4e430974-b0d4-4d8a-a8a5-c7f2eb24b988'	System	01 Feb 2021 21:34:28
User entered 'No (N)'	System	01 Feb 2021 21:34:28

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-02-01T16:34:21', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '4e430974-b0d4-4d8a-a8a5-c7f2eb24b988'	System	01 Feb 2021 21:34:28
User entered 'No (N)'	System	01 Feb 2021 21:34:28

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-02-01T16:34:25', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '4e430974-b0d4-4d8a-a8a5-c7f2eb24b988'	System	01 Feb 2021 21:34:28
User entered '01 Feb 2021 16:34:25'	System	01 Feb 2021 21:34:28

US3632127

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 12:26:41
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 12:26:41

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-02-05T13:51:30', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'acfb49da-a860-4534-8d9b-b7f329705e16'	System	05 Feb 2021 18:51:43
User entered 'No (N)'	System	05 Feb 2021 18:51:43

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-02-05T13:51:34', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'acfb49da-a860-4534-8d9b-b7f329705e16'	System	05 Feb 2021 18:51:43
User entered 'No (N)'	System	05 Feb 2021 18:51:43

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-02-05T13:51:39', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'acfb49da-a860-4534-8d9b-b7f329705e16'	System	05 Feb 2021 18:51:43
User entered '05 Feb 2021 13:51:39'	System	05 Feb 2021 18:51:43

US3632127

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 12:26:41
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 12:26:41

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-02-11T16:07:38', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '18186486-ff8c-4cb5-a54d-36ae7a5c3811'	System	11 Feb 2021 21:07:51
User entered 'No (N)'	System	11 Feb 2021 21:07:51

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-02-11T16:07:43', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '18186486-ff8c-4cb5-a54d-36ae7a5c3811'	System	11 Feb 2021 21:07:51
User entered 'No (N)'	System	11 Feb 2021 21:07:51

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-02-11T16:07:46', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '18186486-ff8c-4cb5-a54d-36ae7a5c3811'	System	11 Feb 2021 21:07:51
User entered '11 Feb 2021 16:07:46'	System	11 Feb 2021 21:07:51

US3632127

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 12:26:41
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 12:26:41

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-02-18T11:39:24', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'c27b7a7c-7e3b-400d-9c9a-ab36feb68e7f'	System	18 Feb 2021 16:39:58
User entered 'No (N)'	System	18 Feb 2021 16:39:58

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-02-18T11:39:33', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'c27b7a7c-7e3b-400d-9c9a-ab36feb68e7f'	System	18 Feb 2021 16:39:58
User entered 'No (N)'	System	18 Feb 2021 16:39:58

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-02-18T11:39:55', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'c27b7a7c-7e3b-400d-9c9a-ab36feb68e7f' User entered '18 Feb 2021 11:39:55'	System	18 Feb 2021 16:39:58
	System	18 Feb 2021 16:39:58

US3632127

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 12:26:41
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 12:26:41

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-02-25T07:13:55-05:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8e45336f-bcdd-4b25-873d-fd5cc961fbdb'	System	25 Feb 2021 12:14:40
User entered 'Yes (Y)'	System	25 Feb 2021 12:14:40

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-02-25T07:14:00-05:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8e45336f-bcdd-4b25-873d-fd5cc961fbdb'	System	25 Feb 2021 12:14:40
User entered 'No (N)'	System	25 Feb 2021 12:14:40

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-02-25T07:14:05-05:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8e45336f-bcdd-4b25-873d-fd5cc961fbdb'	System	25 Feb 2021 12:14:40
User entered 'No (N)'	System	25 Feb 2021 12:14:40

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-02-25T07:14:13-05:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8e45336f-bcdd-4b25-873d-fd5cc961fbdb'	System	25 Feb 2021 12:14:40
User entered 'Yes (Y)'	System	25 Feb 2021 12:14:40

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-02-25T07:14:20-05:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8e45336f-bcdd-4b25-873d-fd5cc961fddb'	System	25 Feb 2021 12:14:40
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Feb 2021 12:14:40

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-02-25T07:14:28-05:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8e45336f-bcdd-4b25-873d-fd5cc961fbbd'	System	25 Feb 2021 12:14:40
User entered '25 Feb 2021 12:14:28'	System	25 Feb 2021 12:14:40

US3632127

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 12:26:41
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 12:26:41

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-03-05T10:34:40-05:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '442c2953-9024-4320-a42d-4a7dc5a0eedb' User entered 'No (N)'	System	05 Mar 2021 15:34:54
	System	05 Mar 2021 15:34:54

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-03-05T10:34:45-05:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '442c2953-9024-4320-a42d-4a7dc5a0eedb' User entered 'No (N)'	System	05 Mar 2021 15:34:54
	System	05 Mar 2021 15:34:54

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-03-05T10:34:49-05:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '442c2953-9024-4320-a42d-4a7dc5a0eedb' User entered '05 Mar 2021 10:34:49'	System	05 Mar 2021 15:34:54
	System	05 Mar 2021 15:34:54

US3632127

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 12:26:41
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 12:26:41

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-03-11T09:14:14-05:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '6c46fdf7-1c14-4d4b-92f9-dbf80fd8888b' User entered 'No (N)'	System	11 Mar 2021 14:14:24
	System	11 Mar 2021 14:14:24

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-03-11T09:14:17-05:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '6c46fdf7-1c14-4d4b-92f9-dbf80fd8888b'	System	11 Mar 2021 14:14:24
User entered 'No (N)'	System	11 Mar 2021 14:14:24

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-03-11T09:14:21-05:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '6c46fdf7-1c14-4d4b-92f9-dbf80fd8888b' User entered '11 Mar 2021 09:14:21'	System	11 Mar 2021 14:14:24
	System	11 Mar 2021 14:14:24

US3632127

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 12:26:41
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 12:26:41

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-03-18T21:43:22-04:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ac0d06c6-1b0d-41f3-8cb2-1bf000c1be1b'	System	19 Mar 2021 01:43:36
User entered 'No (N)'	System	19 Mar 2021 01:43:36

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-03-18T21:43:26-04:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ac0d06c6-1b0d-41f3-8cb2-1bf000c1be1b'	System	19 Mar 2021 01:43:36
User entered 'No (N)'	System	19 Mar 2021 01:43:36

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-03-18T21:43:32-04:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ac0d06c6-1b0d-41f3-8cb2-1bf000c1be1b' User entered '18 Mar 2021 21:43:32'	System	19 Mar 2021 01:43:36
	System	19 Mar 2021 01:43:36

US3632127

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 12:26:41
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 12:26:41

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-03-26T09:48:02-04:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '3448de50-16d2-4dfb-9bc1-0e6477509f71'	System	26 Mar 2021 13:48:14
User entered 'No (N)'	System	26 Mar 2021 13:48:14

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-03-26T09:48:06-04:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '3448de50-16d2-4dfb-9bc1-0e6477509f71'	System	26 Mar 2021 13:48:14
User entered 'No (N)'	System	26 Mar 2021 13:48:14

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-03-26T09:48:10-04:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '3448de50-16d2-4dfb-9bc1-0e6477509f71' User entered '26 Mar 2021 09:48:10'	System	26 Mar 2021 13:48:14
	System	26 Mar 2021 13:48:14

US3632127

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 12:26:41
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 12:26:41

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-04-01T19:58:24-04:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7c5e38dd-9e09-451b-8f46-2b82fbaca8e6'	System	01 Apr 2021 23:58:38
User entered 'No (N)'	System	01 Apr 2021 23:58:38

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-04-01T19:58:28-04:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7c5e38dd-9e09-451b-8f46-2b82fbaca8e6'	System	01 Apr 2021 23:58:38
User entered 'No (N)'	System	01 Apr 2021 23:58:38

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-04-01T19:58:33-04:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7c5e38dd-9e09-451b-8f46-2b82fbaca8e6'	System	01 Apr 2021 23:58:38
User entered '01 Apr 2021 19:58:33'	System	01 Apr 2021 23:58:38

US3632127

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 12:26:41
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 12:26:41

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-04-08T16:44:17-04:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '37582a8b-2901-4e28-bf17-7cbb7a2020ee'	System	08 Apr 2021 20:44:37
User entered 'No (N)'	System	08 Apr 2021 20:44:37

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-04-08T16:44:21-04:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '37582a8b-2901-4e28-bf17-7cbb7a2020ee'	System	08 Apr 2021 20:44:37
User entered 'No (N)'	System	08 Apr 2021 20:44:37

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-04-08T16:44:25-04:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '37582a8b-2901-4e28-bf17-7cbb7a2020ee' User entered '08 Apr 2021 16:44:25'	System	08 Apr 2021 20:44:37
	System	08 Apr 2021 20:44:37

US3632127

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 12:26:41
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 12:26:41

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-04-17T19:12:23-04:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '42c07e32-3d94-4855-b557-5388946349f0'	System	17 Apr 2021 23:12:37
User entered 'No (N)'	System	17 Apr 2021 23:12:37

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-04-17T19:12:27-04:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '42c07e32-3d94-4855-b557-5388946349f0'	System	17 Apr 2021 23:12:37
User entered 'No (N)'	System	17 Apr 2021 23:12:37

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-04-17T19:12:31-04:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '42c07e32-3d94-4855-b557-5388946349f0'	System	17 Apr 2021 23:12:37
User entered '17 Apr 2021 19:12:31'	System	17 Apr 2021 23:12:37

US3632127

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 12:26:41
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 12:26:41

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-04-23T12:32:06-04:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'c638b4db-7d64-43b3-beb2-971500005760'	System	23 Apr 2021 16:32:16
User entered 'No (N)'	System	23 Apr 2021 16:32:16

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-04-23T12:32:09-04:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'c638b4db-7d64-43b3-beb2-971500005760' User entered 'No (N)'	System	23 Apr 2021 16:32:16
	System	23 Apr 2021 16:32:16

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-04-23T12:32:12-04:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'c638b4db-7d64-43b3-beb2-971500005760'	System	23 Apr 2021 16:32:16
User entered '23 Apr 2021 12:32:12'	System	23 Apr 2021 16:32:16

US3632127

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 12:26:41
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 12:26:41

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-04-29T17:48:03-04:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ef3f3b5d-e157-4d58-9559-d0b674c13898'	System	29 Apr 2021 21:48:18
User entered 'No (N)'	System	29 Apr 2021 21:48:18

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-04-29T17:48:09-04:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ef3f3b5d-e157-4d58-9559-d0b674c13898'	System	29 Apr 2021 21:48:18
User entered 'No (N)'	System	29 Apr 2021 21:48:18

US3632127

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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-04-29T17:48:13-04:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ef3f3b5d-e157-4d58-9559-d0b674c13898'	System	29 Apr 2021 21:48:18
User entered '29 Apr 2021 17:48:13'	System	29 Apr 2021 21:48:18

US3632127

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 12:26:41
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '17 Nov 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '21 Nov 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '24 Nov 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '28 Nov 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '01 Dec 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '05 Dec 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '08 Dec 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '12 Dec 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '15 Dec 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

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 12:26:41
Amendment Manager: User entered '19 Dec 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

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 19:45:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-03-05T10:35:02-05:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '139c99aa-785d-4579-8d80-de526f301165'	System	05 Mar 2021 15:35:19
User entered 'No (N)'	System	05 Mar 2021 15:35:19

US3632127

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 19:45:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2021-03-05T10:35:14-05:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '139c99aa-785d-4579-8d80-de526f301165' User entered '05 Mar 2021 10:35:14'	System	05 Mar 2021 15:35:19
	System	05 Mar 2021 15:35:19

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:59:48
User entered 'Yes (Y)'	Isaac Perez (b) (4) (b) (4)	07 Jan 2021 13:52:43

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:59:48
User entered '6 Jan 2021'	Isaac Perez (b) (4)	07 Jan 2021 13:52:43

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:59:48
User entered 'Contact Made (CONTACT MADE)'	Isaac Perez (b) (4)	07 Jan 2021 13:52:43

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:59:48
User entered empty.	Isaac Perez (b) (4) (b) (4)	07 Jan 2021 13:52:43

US3632127

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)	28 Mar 2021 01:33:19
User signature succeeded.	Colleen Kelley (b) (4)	08 Mar 2021 14:44:28
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 20:00:02
User entered 'Yes (Y)'	Isaac Perez (b) (4)	07 Jan 2021 13:52:49

US3632127

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)	28 Mar 2021 01:33:19
User entered '1'	System	07 Jan 2021 13:52:49

US3632127

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 08:50:34
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:06:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Feb 2021 17:53:36

US3632127

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 08:50:34
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:06:00
User entered '12 Feb 2021'	(b) (4), (b) (6)	12 Feb 2021 17:53:36

US3632127

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 08:50:34
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:06:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Feb 2021 17:53:36

US3632127

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 08:50:34
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:06:00
User entered 'Completed while participant was here for OL-2.'	(b) (4), (b) (6)	12 Feb 2021 17:53:36

US3632127

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 08:50:34
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:06:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Feb 2021 17:53:44

US3632127

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 08:50:34
User entered '1'	System	12 Feb 2021 17:53:44

US3632127

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 08:50:34
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:03:48
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
User entered 'Yes (Y)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	11 Mar 2021 14:15:02

US3632127

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 08:50:34
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:03:48
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
User entered '11 Mar 2021'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	11 Mar 2021 14:15:02

US3632127

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 08:50:34
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:03:48
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	05 Apr 2021 01:17:45
User entered 'Contact Made (CONTACT MADE)'	Sarah Wiatrek (b) (4) (b) (4)	11 Mar 2021 14:15:02

US3632127

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 08:50:34
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:03:48
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	05 Apr 2021 01:17:45
User entered empty.	Sarah Wiatrek (b) (4) (b) (4)	11 Mar 2021 14:15:02

US3632127

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 08:50:34
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:04:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
User entered 'Yes (Y)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	11 Mar 2021 14:15:08

US3632127

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 08:50:34
User entered 'I'	System	11 Mar 2021 14:15:08

US3632127

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:56
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:37:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:51:48

US3632127

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)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:56
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:37:15
User entered '9 Apr 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:51:48

US3632127

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)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:56
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:37:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:51:48

US3632127

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)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:56
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:37:15
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:51:48

US3632127

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)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:24
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:37:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:51:53

US3632127

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 12:51:53

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:12:54
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:00
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab1: It appears PPD Central Lab has a Nasopharyngeal Swab Sample with date 11-DEC-2020 under Illness Visit Day 1; however, there is no record in EDC. Please confirm the correct visit and update EDC. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 12:52:41
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab1: It appears PPD Central Lab has a Nasopharyngeal Swab Sample with date 11-DEC-2020 under Illness Visit Day 1; however, there is no record in EDC. Please confirm the correct visit and update EDC. Else clarify, thank you.' answered with 'per source documentation illness visit was done 11DEC2020, blood and NP swabs collected at that time' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 15:09:10
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab1: It appears PPD Central Lab has a Nasopharyngeal Swab Sample with date 11-DEC-2020 under Illness Visit Day 1; however, there is no record in EDC. Please confirm the correct visit and update EDC. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 12:11:38
User entered '11 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 17:37:41

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:12:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:32:25
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:12
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:47:00
User entered '09:00'	(b) (4), (b) (6)	11 Dec 2020 17:37:41

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:12:54
User entered '11 Dec 2020 09:00'	System	11 Dec 2020 17:37:41

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:12:54
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:00
User entered 'Safety Call (Safety Call)'	(b) (4), (b) (6)	11 Dec 2020 17:37:41

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:12:54
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Dec 2020 17:37:41

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:39:12

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:32
User entered '6 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 17:39:46
User entered '7 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 17:39:12

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:32
User entered '0'	(b) (4), (b) (6)	11 Dec 2020 17:39:12

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:32
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Dec 2020 17:39:12

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User entered '%'	System	11 Dec 2020 17:39:12

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:32
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Dec 2020 17:39:12

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:32
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:39:12

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:33:07
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 15:53:27
DataPoint Un-verified.	(b) (4), (b) (6)	24 Feb 2021 18:54:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:53:32
User entered 'Mild (Mild)'	(b) (4), (b) (6)	11 Dec 2020 17:39:12

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:32
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:39:12

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:32
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:39:12

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:32
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:39:12

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:32
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:39:12

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:32
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:39:12

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:32
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:39:12

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:32
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:39:12

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:32
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:39:12

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:32
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:39:12

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:32
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:39:12

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:32
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:39:12

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:32
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:39:12

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:32
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 17:39:46
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:39:12

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:32
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:39:12

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:39:46

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Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:34
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Dec 2020 17:40:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Dec 2020 17:40:55
User entered '7 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 17:40:55
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Dec 2020 17:39:46
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:39:46

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Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:34
User entered '0'	(b) (4), (b) (6)	11 Dec 2020 17:39:46

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Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 17:40:55
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:39:46

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User entered '%'	System	11 Dec 2020 17:40:55
User entered empty.	System	11 Dec 2020 17:39:46

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 17:40:55
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:39:46

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 17:40:55
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:39:46

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:34
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 17:40:55
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:39:46

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 17:40:55
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:39:46

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 17:40:55
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:39:46

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 17:40:55
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:39:46

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 17:40:55
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:39:46

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Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 17:40:55
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:39:46

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 17:40:55
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:39:46

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 17:40:55
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:39:46

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 17:40:55
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:39:46

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 17:40:55
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:39:46

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 17:40:55
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:39:46

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 17:40:55
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:39:46

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 17:40:55
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:39:46

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:34
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 17:40:55
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:39:46

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 17:40:55
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:39:46

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:42:05

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:38
User entered '8 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 17:42:05

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:38
User entered '0'	(b) (4), (b) (6)	11 Dec 2020 17:42:05

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:38
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Dec 2020 17:42:05

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User entered '%'	System	11 Dec 2020 17:42:05

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:38
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Dec 2020 17:42:05

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:38
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:42:05

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:38
User entered 'Mild (Mild)'	(b) (4), (b) (6)	11 Dec 2020 17:42:05

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:38
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:42:05

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:38
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:42:05

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:38
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:42:05

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:38
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:42:05

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:38
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:42:05

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:38
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:42:05

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:38
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:42:05

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:38
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:42:05

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:38
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:42:05

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:38
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:42:05

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:38
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:42:05

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:38
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:42:05

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:38
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:42:05

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:38
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:42:05

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:43:16

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:39
User entered '9 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 17:43:16

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:39
User entered '0'	(b) (4), (b) (6)	11 Dec 2020 17:43:16

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Dec 2020 17:43:16

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User entered '%'	System	11 Dec 2020 17:43:16

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:39
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Dec 2020 17:43:16

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:39
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:43:16

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:39
User entered 'Mild (Mild)'	(b) (4), (b) (6)	11 Dec 2020 17:43:16

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:39
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:43:16

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:39
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:43:16

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:39
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:43:16

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:39
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:43:16

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:39
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:43:16

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:39
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:43:16

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:39
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:43:16

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:39
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:43:16

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:39
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:43:16

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:39
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:43:16

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:39
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:43:16

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:39
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:43:16

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:39
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:43:16

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:39
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:43:16

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:44:10

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:41
User entered '10 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 17:44:10

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:41
User entered '0'	(b) (4), (b) (6)	11 Dec 2020 17:44:10

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:41
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Dec 2020 17:44:10

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User entered '%'	System	11 Dec 2020 17:44:10

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:41
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Dec 2020 17:44:10

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:41
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:44:10

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:41
User entered 'Mild (Mild)'	(b) (4), (b) (6)	11 Dec 2020 17:44:10

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:41
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:44:10

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:41
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:44:10

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:41
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:44:10

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:41
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:44:10

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:41
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:44:10

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:41
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:44:10

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:41
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:44:10

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:41
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:44:10

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:41
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:44:10

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:41
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:44:10

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:41
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:44:10

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:41
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:44:10

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:41
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:44:10

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:53:41
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:44:10

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:46:01

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:53
User entered '11 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 17:46:01

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:53
User entered '0'	(b) (4), (b) (6)	11 Dec 2020 17:46:01

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:53
User entered '99'	(b) (4), (b) (6)	11 Dec 2020 17:46:01

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User entered '%'	System	11 Dec 2020 17:46:01

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:53
User entered '98.7' F	(b) (4), (b) (6)	11 Dec 2020 17:46:01

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:53
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:46:01

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:53
User entered 'Mild (Mild)'	(b) (4), (b) (6)	11 Dec 2020 17:46:01

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:53
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:46:01

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:53
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:46:01

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:53
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:46:01

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:53
User entered 'Mild (Mild)'	(b) (4), (b) (6)	11 Dec 2020 17:46:01

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:53
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:46:01

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:53
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:46:01

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:53
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:46:01

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:53
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:46:01

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:53
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:46:01

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:53
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:46:01

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:53
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:46:01

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:53
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:46:01

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:53
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:46:01

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:53
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:46:01

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	12 Dec 2020 22:19:28

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:57
User entered '12 Dec 2020'	(b) (4), (b) (6)	12 Dec 2020 22:19:28

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:57
User entered '0'	(b) (4), (b) (6)	12 Dec 2020 22:19:28

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:57
User entered '96'	(b) (4), (b) (6)	12 Dec 2020 22:19:28

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User entered '%'	System	12 Dec 2020 22:19:28

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:57
User entered '98.1' F	(b) (4), (b) (6)	12 Dec 2020 22:19:28

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:57
User entered 'None (None)'	(b) (4), (b) (6)	12 Dec 2020 22:19:28

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:57
User entered 'None (None)'	(b) (4), (b) (6)	12 Dec 2020 22:19:28

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:57
User entered 'None (None)'	(b) (4), (b) (6)	12 Dec 2020 22:19:28

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:57
User entered 'None (None)'	(b) (4), (b) (6)	12 Dec 2020 22:19:28

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:57
User entered 'None (None)'	(b) (4), (b) (6)	12 Dec 2020 22:19:28

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:57
User entered 'None (None)'	(b) (4), (b) (6)	12 Dec 2020 22:19:28

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:57
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Dec 2020 22:19:28

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:57
User entered 'None (None)'	(b) (4), (b) (6)	12 Dec 2020 22:19:28

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:57
User entered 'None (None)'	(b) (4), (b) (6)	12 Dec 2020 22:19:28

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:57
User entered 'None (None)'	(b) (4), (b) (6)	12 Dec 2020 22:19:28

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:57
User entered 'None (None)'	(b) (4), (b) (6)	12 Dec 2020 22:19:28

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:57
User entered 'None (None)'	(b) (4), (b) (6)	12 Dec 2020 22:19:28

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:57
User entered 'None (None)'	(b) (4), (b) (6)	12 Dec 2020 22:19:28

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:57
User entered 'None (None)'	(b) (4), (b) (6)	12 Dec 2020 22:19:28

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:57
User entered 'None (None)'	(b) (4), (b) (6)	12 Dec 2020 22:19:28

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:57
User entered 'None (None)'	(b) (4), (b) (6)	12 Dec 2020 22:19:28

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	13 Dec 2020 21:24:41

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:58
User entered '13 Dec 2020'	(b) (4), (b) (6)	13 Dec 2020 21:24:41

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:58
User entered '0'	(b) (4), (b) (6)	13 Dec 2020 21:24:41

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:58
User entered '98'	(b) (4), (b) (6)	13 Dec 2020 21:24:41

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User entered '%'	System	13 Dec 2020 21:24:41

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:58
User entered '97.9' F	(b) (4), (b) (6)	13 Dec 2020 21:24:41

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:58
User entered 'None (None)'	(b) (4), (b) (6)	13 Dec 2020 21:24:41

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:58
User entered 'None (None)'	(b) (4), (b) (6)	13 Dec 2020 21:24:41

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:58
User entered 'None (None)'	(b) (4), (b) (6)	13 Dec 2020 21:24:41

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:58
User entered 'None (None)'	(b) (4), (b) (6)	13 Dec 2020 21:24:41

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:58
User entered 'None (None)'	(b) (4), (b) (6)	13 Dec 2020 21:24:41

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:58
User entered 'None (None)'	(b) (4), (b) (6)	13 Dec 2020 21:24:41

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:58
User entered 'None (None)'	(b) (4), (b) (6)	13 Dec 2020 21:24:41

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:58
User entered 'None (None)'	(b) (4), (b) (6)	13 Dec 2020 21:24:41

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:58
User entered 'None (None)'	(b) (4), (b) (6)	13 Dec 2020 21:24:41

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:58
User entered 'None (None)'	(b) (4), (b) (6)	13 Dec 2020 21:24:41

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:58
User entered 'Mild (Mild)'	(b) (4), (b) (6)	13 Dec 2020 21:24:41

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:58
User entered 'None (None)'	(b) (4), (b) (6)	13 Dec 2020 21:24:41

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:58
User entered 'None (None)'	(b) (4), (b) (6)	13 Dec 2020 21:24:41

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:58
User entered 'None (None)'	(b) (4), (b) (6)	13 Dec 2020 21:24:41

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:58
User entered 'None (None)'	(b) (4), (b) (6)	13 Dec 2020 21:24:41

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:58
User entered 'None (None)'	(b) (4), (b) (6)	13 Dec 2020 21:24:41

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Day 9 (Day 9)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:15:59

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:00
User entered '14 Dec 2020'	(b) (4), (b) (6)	14 Dec 2020 21:15:59

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:00
User entered '0'	(b) (4), (b) (6)	14 Dec 2020 21:15:59

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:00
User entered '96'	(b) (4), (b) (6)	14 Dec 2020 21:15:59

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:13:01
User entered '%'	System	14 Dec 2020 21:15:59

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:00
User entered '97.9' F	(b) (4), (b) (6)	14 Dec 2020 21:15:59

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:00
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 21:15:59

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:00
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 21:15:59

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:00
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 21:15:59

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:00
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 21:15:59

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:00
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 21:15:59

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:00
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 21:15:59

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:00
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 21:15:59

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:00
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 21:15:59

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:00
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 21:15:59

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:00
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 21:15:59

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:00
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 21:15:59

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:00
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 21:15:59

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:00
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 21:15:59

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:00
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 21:15:59

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:00
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 21:15:59

US3632127

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:13:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:00
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 21:15:59

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:06
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:41:22
User entered '11 Dec 2020'	(b) (4), (b) (6)	15 Dec 2020 14:00:10

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:06
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:41:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 14:00:10

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:06
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:41:22
User entered 'No (N)'	(b) (4), (b) (6)	15 Dec 2020 14:00:10

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:06
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:41:22
User entered '11 Dec 2020'	(b) (4), (b) (6)	15 Dec 2020 14:00:10

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:06
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:41:22
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	15 Dec 2020 14:00:10

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:06
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:41:22
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:00:10

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:06
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:41:22
User entered 'No (N)'	(b) (4), (b) (6)	15 Dec 2020 14:00:10

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:06
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:41:22
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:00:10

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:06
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:41:22
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:00:10

US3632127

Folder: Covid-19 Assessment 11 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)	04 May 2021 00:13:06
User entered '0'	System	15 Dec 2020 14:00:10

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:07
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:31:09
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:37:15
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:51:38
Signature has been broken.	(b) (4), (b) (6)	09 Apr 2021 16:51:38
User entered '18 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 16:51:38
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:15
User entered '30 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 16:04:15

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:49:40
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 18:22:34
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:13:15
User entered '08:00'	(b) (4), (b) (6)	30 Nov 2020 16:04:15

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:07
User entered '18 Nov 2020 08:00'	System	09 Apr 2021 16:51:38
User entered '30 Nov 2020 08:00'	System	30 Nov 2020 16:04:15

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:07
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:42:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:49:43
User closed query 'Please confirm if this was a clinic visit; the source notes a safety call was completed. ' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 17:49:37
Query 'Please confirm if this was a clinic visit; the source notes a safety call was completed. ' answered with 'confirmed contact was safety call, corrected.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:43:30
Signature has been broken.	(b) (4), (b) (6)	16 Apr 2021 14:43:16
User entered 'Safety Call (Safety Call)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 14:43:16
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 18:29:42
User opened query 'Please confirm if this was a clinic visit; the source notes a safety call was completed. ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 18:29:39
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:13:15
User entered 'Clinical Visit - Un-scheduled (Clinical Visit - Un-scheduled)'	(b) (4), (b) (6)	30 Nov 2020 16:04:15

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:07
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Nov 2020 16:04:15

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 16:05:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:32
User entered '17 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 16:05:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:32
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 16:05:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:32
User entered missing code ND - Not Done.	(b) (4), (b) (6)	30 Nov 2020 16:05:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User entered '%'	System	30 Nov 2020 16:05:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:32
User entered missing code ND - Not Done.	(b) (4), (b) (6)	30 Nov 2020 16:05:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:32
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:05:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:32
User entered 'Mild (Mild)'	(b) (4), (b) (6)	30 Nov 2020 16:05:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:32
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:05:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:32
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:05:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:32
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:05:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:32
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:05:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:32
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:05:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:32
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:05:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:32
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:05:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:32
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:05:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:32
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:05:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:32
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:05:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:32
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:05:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:32
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:05:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:32
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:05:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:32
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:05:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 16:07:34

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:34
User entered '18 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 16:07:34

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:34
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 16:07:34

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:34
User entered missing code ND - Not Done.	(b) (4), (b) (6)	30 Nov 2020 16:07:34

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User entered '%'	System	30 Nov 2020 16:07:34

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:34
User entered missing code ND - Not Done.	(b) (4), (b) (6)	30 Nov 2020 16:07:34

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:34
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:07:34

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:34
User entered 'Mild (Mild)'	(b) (4), (b) (6)	30 Nov 2020 16:07:34

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:34
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:07:34

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:34
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:07:34

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:34
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:07:34

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:34
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:07:34

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:34
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:07:34

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:34
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:07:34

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:34
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:07:34

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:34
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:07:34

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:34
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:07:34

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:34
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:07:34

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:34
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:07:34

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:34
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:07:34

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:34
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:07:34

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:34
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:07:34

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 16:08:44

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:36
User entered '19 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 16:08:44

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:36
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 16:08:44

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:36
User entered missing code ND - Not Done.	(b) (4), (b) (6)	30 Nov 2020 16:08:44

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User entered '%'	System	30 Nov 2020 16:08:44

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:36
User entered missing code ND - Not Done.	(b) (4), (b) (6)	30 Nov 2020 16:08:44

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:36
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:08:44

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:36
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:08:44

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:36
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:08:44

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:36
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:08:44

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:36
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:08:44

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:36
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:08:44

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:36
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:08:44

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:36
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:08:44

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:36
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:08:44

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:36
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:08:44

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:36
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:08:44

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:36
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:08:44

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:36
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:08:44

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:36
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:08:44

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:36
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:08:44

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:36
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:08:44

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 16:09:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:41
User entered '20 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 16:09:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:41
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 16:09:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:41
User entered missing code ND - Not Done.	(b) (4), (b) (6)	30 Nov 2020 16:09:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User entered '%'	System	30 Nov 2020 16:09:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:41
User entered missing code ND - Not Done.	(b) (4), (b) (6)	30 Nov 2020 16:09:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:41
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:09:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:41
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:09:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:41
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:09:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:41
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:09:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:41
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:09:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:41
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:09:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:41
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:09:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:41
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:09:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:41
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:09:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:41
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:09:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:41
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:09:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:41
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:09:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:41
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:09:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:41
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:09:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:41
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:09:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:41
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:09:36

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 16:10:33

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered '21 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 16:10:33

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 16:10:33

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered missing code ND - Not Done.	(b) (4), (b) (6)	30 Nov 2020 16:10:33

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User entered '%'	System	30 Nov 2020 16:10:33

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered missing code ND - Not Done.	(b) (4), (b) (6)	30 Nov 2020 16:10:33

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:10:33

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:10:33

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:10:33

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:10:33

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:10:33

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:10:33

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:10:33

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:10:33

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:10:33

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:10:33

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:10:33

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:10:33

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:10:33

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:10:33

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:10:33

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:10:33

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 16:11:59

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered '22 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 16:11:59

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Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 16:11:59

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered missing code ND - Not Done.	(b) (4), (b) (6)	30 Nov 2020 16:11:59

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User entered '%'	System	30 Nov 2020 16:11:59

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered missing code ND - Not Done.	(b) (4), (b) (6)	30 Nov 2020 16:11:59

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:11:59

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:11:59

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:11:59

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:11:59

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:11:59

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:11:59

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:11:59

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:11:59

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:11:59

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:11:59

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:11:59

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:11:59

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:11:59

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:11:59

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:11:59

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:11:59

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 16:13:24

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:54
User entered '23 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 16:13:24

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:54
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 16:13:24

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:54
User entered missing code ND - Not Done.	(b) (4), (b) (6)	30 Nov 2020 16:13:24

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Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User entered '%'	System	30 Nov 2020 16:13:24

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:54
User entered missing code ND - Not Done.	(b) (4), (b) (6)	30 Nov 2020 16:13:24

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:54
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:13:24

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:54
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:13:24

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:54
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:13:24

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:54
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:13:24

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:54
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:13:24

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:54
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:13:24

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:54
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:13:24

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:54
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:13:24

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:54
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:13:24

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:54
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:13:24

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:54
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:13:24

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:54
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:13:24

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:54
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:13:24

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:54
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:13:24

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:54
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:13:24

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:54
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:13:24

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 16:14:27

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered '24 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 16:14:27

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 16:14:27

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered missing code ND - Not Done.	(b) (4), (b) (6)	30 Nov 2020 16:14:27

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User entered '%'	System	30 Nov 2020 16:14:27

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered missing code ND - Not Done.	(b) (4), (b) (6)	30 Nov 2020 16:14:27

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:14:27

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:14:27

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:14:27

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:14:27

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:14:27

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:14:27

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:14:27

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:14:27

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:14:27

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:14:27

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:14:27

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:14:27

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:14:27

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:14:27

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:14:27

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:14:27

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Day 9 (Day 9)'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 16:15:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered '25 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 16:15:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 16:15:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered missing code ND - Not Done.	(b) (4), (b) (6)	30 Nov 2020 16:15:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User entered '%'	System	30 Nov 2020 16:15:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered missing code ND - Not Done.	(b) (4), (b) (6)	30 Nov 2020 16:15:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:15:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:15:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:15:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:15:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:15:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:15:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:15:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:15:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:15:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:15:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:15:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:15:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:15:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:15:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:15:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:08:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:13:55
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:15:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:08:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Day 10 (Day 10)'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 16:16:27

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:08:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:10
User entered '26 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 16:16:27

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:08:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:10
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 16:16:27

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:10
User entered missing code ND - Not Done.	(b) (4), (b) (6)	30 Nov 2020 16:16:27

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User entered '%'	System	30 Nov 2020 16:16:27

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:08:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:10
User entered missing code ND - Not Done.	(b) (4), (b) (6)	30 Nov 2020 16:16:27

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:08:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:10
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:16:27

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:08:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:10
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:16:27

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:08:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:10
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:16:27

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:08:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:10
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:16:27

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:08:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:10
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:16:27

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:08:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:10
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:16:27

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:08:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:10
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:16:27

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:08:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:10
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:16:27

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:10
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:16:27

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:10
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:16:27

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:08:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:10
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:16:27

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:08:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:10
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:16:27

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:08:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:10
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:16:27

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:08:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:10
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:16:27

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:08:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:10
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:16:27

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:08:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:10
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:16:27

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:08:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Day 11 (Day 11)'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 16:18:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:08:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:36:17
User entered '27 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 16:18:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:08:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:36:17
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 16:18:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:36:17
User entered missing code ND - Not Done.	(b) (4), (b) (6)	30 Nov 2020 16:18:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User entered '%'	System	30 Nov 2020 16:18:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:08:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:36:17
User entered missing code ND - Not Done.	(b) (4), (b) (6)	30 Nov 2020 16:18:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:08:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:36:17
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:18:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:08:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:36:17
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:18:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:08:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:36:17
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:18:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:08:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:36:17
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:18:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:08:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:36:17
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:18:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:08:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:36:17
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:18:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:08:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:36:17
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:18:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:08:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:36:17
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:18:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:36:17
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:18:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:36:17
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:18:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:08:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:36:17
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:18:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:08:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:36:17
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:18:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:08:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:36:17
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:18:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:08:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:36:17
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:18:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:08:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:36:17
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:18:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:08:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:36:17
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:18:22

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:08:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Day 12 (Day 12)'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 16:20:25

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:08:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:14
User entered '28 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 16:20:25

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:08:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:14
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 16:20:25

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:14
User entered missing code ND - Not Done.	(b) (4), (b) (6)	30 Nov 2020 16:20:25

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User entered '%'	System	30 Nov 2020 16:20:25

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:08:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:14
User entered missing code ND - Not Done.	(b) (4), (b) (6)	30 Nov 2020 16:20:25

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:08:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:14
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:20:25

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:08:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:14
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:20:25

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:08:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:14
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:20:25

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:08:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:14
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:20:25

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:08:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:14
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:20:25

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:08:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:14
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:20:25

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:08:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:14
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:20:25

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:08:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:14
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:20:25

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:14
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:20:25

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:14
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:20:25

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:08:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:14
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:20:25

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:08:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:14
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:20:25

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:08:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:14
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:20:25

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:08:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:14
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:20:25

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:08:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:14
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:20:25

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:08:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:14
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:20:25

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:08:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Day 13 (Day 13)'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 16:21:31

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:08:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:16
User entered '29 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 16:21:31

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:08:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:16
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 16:21:31

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:16
User entered missing code ND - Not Done.	(b) (4), (b) (6)	30 Nov 2020 16:21:31

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User entered '%'	System	30 Nov 2020 16:21:31

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:08:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:16
User entered missing code ND - Not Done.	(b) (4), (b) (6)	30 Nov 2020 16:21:31

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:08:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:16
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:21:31

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:08:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:16
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:21:31

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:08:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:16
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:21:31

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:08:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:16
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:21:31

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:08:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:16
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:21:31

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:08:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:16
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:21:31

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:08:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:16
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:21:31

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:08:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:16
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:21:31

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:16
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:21:31

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:16
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:21:31

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:08:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:16
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:21:31

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:08:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:16
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:21:31

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:08:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:16
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:21:31

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:08:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:16
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:21:31

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:08:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:16
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:21:31

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:08:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:16
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:21:31

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:08:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Day 14 (Day 14)'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 16:23:14

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:08:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:20
User entered '30 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 16:23:14

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:08:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:20
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 16:23:14

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:20
User entered '97'	(b) (4), (b) (6)	30 Nov 2020 16:23:14

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User entered '%'	System	30 Nov 2020 16:23:14

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:08:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:20
User entered '97' F	(b) (4), (b) (6)	30 Nov 2020 16:23:14

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:08:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:20
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:23:14

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:08:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:20
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:23:14

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:08:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:20
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:23:14

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:08:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:20
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:23:14

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:08:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:20
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:23:14

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:08:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:20
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:23:14

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:08:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:20
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:23:14

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:08:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:20
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:23:14

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:20
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:23:14

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:20
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:23:14

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:08:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:20
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:23:14

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:08:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:20
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:23:14

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:08:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:20
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:23:14

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:08:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:20
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:23:14

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:08:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:20
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:23:14

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:08:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:20
User entered 'None (None)'	(b) (4), (b) (6)	30 Nov 2020 16:23:14

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:08:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Day 15 (Day 15)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:37:13

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:08:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:23
User entered '1 Dec 2020'	(b) (4), (b) (6)	01 Dec 2020 21:37:13

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:08:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:23
User entered '0'	(b) (4), (b) (6)	01 Dec 2020 21:37:13

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:23
User entered '96'	(b) (4), (b) (6)	01 Dec 2020 21:37:13

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User entered '%'	System	01 Dec 2020 21:37:13

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:08:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:23
User entered '98.4' F	(b) (4), (b) (6)	01 Dec 2020 21:37:13

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:08:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:23
User entered 'None (None)'	(b) (4), (b) (6)	01 Dec 2020 21:37:13

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:08:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:23
User entered 'None (None)'	(b) (4), (b) (6)	01 Dec 2020 21:37:13

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:08:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:23
User entered 'None (None)'	(b) (4), (b) (6)	01 Dec 2020 21:37:13

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:08:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:23
User entered 'None (None)'	(b) (4), (b) (6)	01 Dec 2020 21:37:13

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:08:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:23
User entered 'None (None)'	(b) (4), (b) (6)	01 Dec 2020 21:37:13

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:08:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:23
User entered 'None (None)'	(b) (4), (b) (6)	01 Dec 2020 21:37:13

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:08:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:23
User entered 'None (None)'	(b) (4), (b) (6)	01 Dec 2020 21:37:13

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:08:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:23
User entered 'None (None)'	(b) (4), (b) (6)	01 Dec 2020 21:37:13

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:23
User entered 'None (None)'	(b) (4), (b) (6)	01 Dec 2020 21:37:13

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:23
User entered 'None (None)'	(b) (4), (b) (6)	01 Dec 2020 21:37:13

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:08:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:23
User entered 'None (None)'	(b) (4), (b) (6)	01 Dec 2020 21:37:13

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:08:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:23
User entered 'None (None)'	(b) (4), (b) (6)	01 Dec 2020 21:37:13

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:08:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:23
User entered 'None (None)'	(b) (4), (b) (6)	01 Dec 2020 21:37:13

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:08:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:23
User entered 'None (None)'	(b) (4), (b) (6)	01 Dec 2020 21:37:13

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:08:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:23
User entered 'None (None)'	(b) (4), (b) (6)	01 Dec 2020 21:37:13

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:08:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:14:23
User entered 'None (None)'	(b) (4), (b) (6)	01 Dec 2020 21:37:13

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:08:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Day 16 (Day 16)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:05:50

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:08:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:40
User entered '2 Dec 2020'	(b) (4), (b) (6)	03 Dec 2020 15:05:50

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:08:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:40
User entered 'l'	(b) (4), (b) (6)	03 Dec 2020 15:05:50

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:40
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 15:05:50

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User entered empty.	System	03 Dec 2020 15:05:50

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:08:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:40
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 15:05:50

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:08:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:40
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 15:05:50

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:08:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:40
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 15:05:50

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:08:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:40
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 15:05:50

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:08:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:40
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 15:05:50

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:08:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:40
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 15:05:50

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:08:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:40
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 15:05:50

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:08:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:40
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 15:05:50

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:08:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:40
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 15:05:50

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:40
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 15:05:50

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:40
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 15:05:50

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:08:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:40
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 15:05:50

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:08:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:40
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 15:05:50

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:08:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:40
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 15:05:50

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:08:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:40
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 15:05:50

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:08:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:40
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 15:05:50

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:08:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:40
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 15:05:50

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:08:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Day 17 (Day 17)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 21:18:33

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:08:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:45
User entered '3 Dec 2020'	(b) (4), (b) (6)	03 Dec 2020 21:18:33

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:08:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:45
User entered '0'	(b) (4), (b) (6)	03 Dec 2020 21:18:33

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:45
User entered '97'	(b) (4), (b) (6)	03 Dec 2020 21:18:33

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:08:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User entered '%'	System	03 Dec 2020 21:18:33

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:08:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:45
User entered '98.2' F	(b) (4), (b) (6)	03 Dec 2020 21:18:33

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:08:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:45
User entered 'None (None)'	(b) (4), (b) (6)	03 Dec 2020 21:18:33

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:08:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:45
User entered 'None (None)'	(b) (4), (b) (6)	03 Dec 2020 21:18:33

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:08:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:45
User entered 'None (None)'	(b) (4), (b) (6)	03 Dec 2020 21:18:33

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:08:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:45
User entered 'None (None)'	(b) (4), (b) (6)	03 Dec 2020 21:18:33

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:08:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:45
User entered 'None (None)'	(b) (4), (b) (6)	03 Dec 2020 21:18:33

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:08:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:45
User entered 'None (None)'	(b) (4), (b) (6)	03 Dec 2020 21:18:33

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:08:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:45
User entered 'None (None)'	(b) (4), (b) (6)	03 Dec 2020 21:18:33

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:08:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:45
User entered 'None (None)'	(b) (4), (b) (6)	03 Dec 2020 21:18:33

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:45
User entered 'None (None)'	(b) (4), (b) (6)	03 Dec 2020 21:18:33

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:08:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:45
User entered 'None (None)'	(b) (4), (b) (6)	03 Dec 2020 21:18:33

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:08:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:45
User entered 'None (None)'	(b) (4), (b) (6)	03 Dec 2020 21:18:33

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:08:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:45
User entered 'Mild (Mild)'	(b) (4), (b) (6)	03 Dec 2020 21:18:33

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:08:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:45
User entered 'None (None)'	(b) (4), (b) (6)	03 Dec 2020 21:18:33

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:08:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:45
User entered 'None (None)'	(b) (4), (b) (6)	03 Dec 2020 21:18:33

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:08:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:45
User entered 'None (None)'	(b) (4), (b) (6)	03 Dec 2020 21:18:33

US3632127

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:08:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:12:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:34:45
User entered 'None (None)'	(b) (4), (b) (6)	03 Dec 2020 21:18:33

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:25
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:37:03
User entered '30 Nov 2020'	(b) (4), (b) (6)	04 Dec 2020 14:30:22

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:25
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:37:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Dec 2020 14:30:22

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:25
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:37:03
User entered 'No (N)'	(b) (4), (b) (6)	04 Dec 2020 14:30:22

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:25
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:37:03
User entered '30 Nov 2020'	(b) (4), (b) (6)	04 Dec 2020 14:30:22

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:25
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:37:03
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	04 Dec 2020 14:30:22

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:25
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:37:03
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 14:30:22

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:25
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:37:03
User entered 'No (N)'	(b) (4), (b) (6)	04 Dec 2020 14:30:22

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:25
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:37:03
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 14:30:22

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:25
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:37:03
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 14:30:22

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:25
User entered '0'	System	04 Dec 2020 14:30:22

US3632127

Folder: Covid-19 Assessment 18 Nov 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)	04 May 2021 00:12:31
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:37:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Dec 2020 17:36:42

US3632127

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)	02 May 2021 20:10:13
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	02 Dec 2020 17:10:27

US3632127

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)	02 May 2021 20:10:13
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:34:56
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 17:10:27

US3632127

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)	02 May 2021 20:10:13
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:34:56
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered '2 Dec 2020'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 17:10:27

US3632127

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)	02 May 2021 20:10:13
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	02 Dec 2020 17:10:27

US3632127

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)	02 May 2021 20:10:13
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:34:56
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	04 Dec 2020 14:32:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 14:32:09
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	(b) (4), (b) (6)	04 Dec 2020 14:32:09
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 17:10:27
User entered empty.	(b) (4), (b) (6)	02 Dec 2020 17:10:27

US3632127

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)	02 May 2021 20:10:13
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:34:56
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 17:10:27

US3632127

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)	02 May 2021 20:10:13
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	02 Dec 2020 17:10:27

US3632127

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)	02 May 2021 20:10:13
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:34:56
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	04 Dec 2020 14:32:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 14:32:09
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	(b) (4), (b) (6)	04 Dec 2020 14:32:09
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 17:10:27
User entered empty.	(b) (4), (b) (6)	02 Dec 2020 17:10:27

US3632127

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)	02 May 2021 20:10:13
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:34:56
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 17:10:27

US3632127

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)	02 May 2021 20:10:13
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	02 Dec 2020 17:10:27

US3632127

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)	02 May 2021 20:10:13
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:34:56
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	04 Dec 2020 14:32:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 14:32:09
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	(b) (4), (b) (6)	04 Dec 2020 14:32:09
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 17:10:27
User entered empty.	(b) (4), (b) (6)	02 Dec 2020 17:10:27

US3632127

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)	02 May 2021 20:10:13
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:34:56
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 17:10:27

US3632127

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)	02 May 2021 20:10:13
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	02 Dec 2020 17:10:27

US3632127

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)	02 May 2021 20:10:13
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:34:56
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	04 Dec 2020 14:32:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 14:32:09
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	(b) (4), (b) (6)	04 Dec 2020 14:32:09
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 17:10:27
User entered empty.	(b) (4), (b) (6)	02 Dec 2020 17:10:27

US3632127

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)	02 May 2021 20:10:13
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:34:56
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 17:10:27

US3632127

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)	02 May 2021 20:10:13
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	02 Dec 2020 17:10:27

US3632127

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)	02 May 2021 20:10:13
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:34:56
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	04 Dec 2020 14:32:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 14:32:09
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	(b) (4), (b) (6)	04 Dec 2020 14:32:09
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 17:10:27
User entered empty.	(b) (4), (b) (6)	02 Dec 2020 17:10:27

US3632127

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)	02 May 2021 20:10:13
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:34:56
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 17:10:27

US3632127

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)	02 May 2021 20:10:13
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	02 Dec 2020 17:10:27

US3632127

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)	02 May 2021 20:10:13
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:34:56
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	04 Dec 2020 14:32:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 14:32:09
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	(b) (4), (b) (6)	04 Dec 2020 14:32:09
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 17:10:27
User entered empty.	(b) (4), (b) (6)	02 Dec 2020 17:10:27

US3632127

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)	02 May 2021 20:10:13
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:34:56
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 17:10:27

US3632127

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:08:05

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	13 Dec 2020 21:25:42

US3632127

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:08:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:24
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Dec 2020 21:25:42

US3632127

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:08:05

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:24
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 13DEC2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 05:13:34
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 13DEC2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'Day 3 saliva resulted in PPD on 17DEC2020. Accession number 1F60MI1' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 16:41:06
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 13DEC2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 06:13:23
User entered '13 Dec 2020'	(b) (4), (b) (6)	13 Dec 2020 21:25:42

US3632127

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:08:05

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	13 Dec 2020 21:25:42

US3632127

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:08:05

Was Saliva Collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:24
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Dec 2020 14:00:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Dec 2020 14:00:26
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Dec 2020 14:00:26
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Dec 2020 21:25:42
User entered empty.	(b) (4), (b) (6)	13 Dec 2020 21:25:42

US3632127

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:08:05

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:24
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Dec 2020 21:25:42

US3632127

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:08:05

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	13 Dec 2020 21:25:42

US3632127

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:08:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:24
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Dec 2020 14:00:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Dec 2020 14:00:26
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Dec 2020 14:00:26
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Dec 2020 21:25:42
User entered empty.	(b) (4), (b) (6)	13 Dec 2020 21:25:42

US3632127

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:08:05

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:24
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Dec 2020 21:25:42

US3632127

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:08:05

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	13 Dec 2020 21:25:42

US3632127

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:08:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:24
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Dec 2020 14:00:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Dec 2020 14:00:26
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Dec 2020 14:00:26
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Dec 2020 21:25:42
User entered empty.	(b) (4), (b) (6)	13 Dec 2020 21:25:42

US3632127

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:08:05

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:24
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Dec 2020 21:25:42

US3632127

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:08:05

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	13 Dec 2020 21:25:42

US3632127

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:08:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:24
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Dec 2020 14:00:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Dec 2020 14:00:26
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Dec 2020 14:00:26
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Dec 2020 21:25:42
User entered empty.	(b) (4), (b) (6)	13 Dec 2020 21:25:42

US3632127

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:08:05

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:24
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Dec 2020 21:25:42

US3632127

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:08:05

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	13 Dec 2020 21:25:42

US3632127

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:08:05

Was Saliva Collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:24
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Dec 2020 14:00:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Dec 2020 14:00:26
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Dec 2020 14:00:26
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Dec 2020 21:25:42
User entered empty.	(b) (4), (b) (6)	13 Dec 2020 21:25:42

US3632127

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:08:05

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:24
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Dec 2020 21:25:42

US3632127

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:08:05

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	13 Dec 2020 21:25:42

US3632127

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:08:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:24
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Dec 2020 14:00:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Dec 2020 14:00:26
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Dec 2020 14:00:26
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Dec 2020 21:25:42
User entered empty.	(b) (4), (b) (6)	13 Dec 2020 21:25:42

US3632127

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:08:05

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:24
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Dec 2020 21:25:42

US3632127

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)	02 May 2021 20:09:57
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:22:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Nov 2020 16:24:26

US3632127

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)	02 May 2021 20:09:57
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:22:31
User entered '30 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 16:24:26

US3632127

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)	02 May 2021 20:09:57
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:22:31
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	30 Nov 2020 16:24:26

US3632127

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)	02 May 2021 20:09:57
User entered 'SICKD1'	System	30 Nov 2020 16:24:26

US3632127

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)	02 May 2021 20:10:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:22:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Nov 2020 16:25:39

US3632127

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)	02 May 2021 20:10:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:22:57
User entered '30 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 16:25:39

US3632127

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)	02 May 2021 20:10:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:22:57
User entered '08:16'	(b) (4), (b) (6)	30 Nov 2020 16:25:39

US3632127

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)	02 May 2021 20:10:01
User entered '30 Nov 2020 08:16'	System	30 Nov 2020 16:25:39

US3632127

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)	02 May 2021 20:10:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:22:57
User entered '64.5' in	(b) (4), (b) (6)	30 Nov 2020 16:25:39
DataPoint set to visible.	System	30 Nov 2020 16:24:26

US3632127

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)	02 May 2021 20:10:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:22:57
User entered '245.4' lb	(b) (4), (b) (6)	30 Nov 2020 16:25:39
DataPoint set to visible.	System	30 Nov 2020 16:24:26

US3632127

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)	02 May 2021 20:10:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:22:57
User entered '97' F	(b) (4), (b) (6)	30 Nov 2020 16:25:39

US3632127

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)	02 May 2021 20:10:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:22:57
User entered 'Oral (Oral)'	(b) (4), (b) (6)	30 Nov 2020 16:25:39

US3632127

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)	02 May 2021 20:10:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:22:57
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 16:25:39

US3632127

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)	02 May 2021 20:10:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:22:57
User entered '75'	(b) (4), (b) (6)	30 Nov 2020 16:25:39

US3632127

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)	02 May 2021 20:10:01
User entered 'bpm'	System	30 Nov 2020 16:25:39

US3632127

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)	02 May 2021 20:10:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:22:57
User entered '14'	(b) (4), (b) (6)	30 Nov 2020 16:25:39

US3632127

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)	02 May 2021 20:10:01
User entered 'breaths/min'	System	30 Nov 2020 16:25:39

US3632127

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)	02 May 2021 20:10:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:22:57
User entered '101'	(b) (4), (b) (6)	30 Nov 2020 16:25:39

US3632127

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)	02 May 2021 20:10:01
User entered 'mmHg'	System	30 Nov 2020 16:25:39

US3632127

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)	02 May 2021 20:10:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:22:57
User entered '71'	(b) (4), (b) (6)	30 Nov 2020 16:25:39

US3632127

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)	02 May 2021 20:10:01
User entered 'mmHg'	System	30 Nov 2020 16:25:39

US3632127

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)	02 May 2021 20:10:01

US3632127

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)	02 May 2021 20:10:01

US3632127

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)	02 May 2021 20:10:04
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:23:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Nov 2020 16:25:54

US3632127

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)	02 May 2021 20:10:04
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:23:10
User entered '30 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 16:25:54

US3632127

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)	02 May 2021 20:10:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:23:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Nov 2020 16:26:05

US3632127

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)	02 May 2021 20:10:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:23:26
User entered '30 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 16:26:05

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:02:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Dec 2020 17:46:42

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:02:52
User entered '11 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 17:46:42

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:02:52
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Dec 2020 17:46:42

US3632127

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	11 Dec 2020 17:46:42

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:03:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Dec 2020 17:47:46

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:03:00
User entered '11 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 17:47:46

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:03:00
User entered '11:10'	(b) (4), (b) (6)	11 Dec 2020 17:47:46

US3632127

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)
User entered '11 Dec 2020 11:10'	System	11 Dec 2020 17:47:46

US3632127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:03:00
User entered '64.5' in	(b) (4), (b) (6)	11 Dec 2020 17:47:46
DataPoint set to visible.	System	11 Dec 2020 17:46:42

US3632127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:03:00
User entered '247.6' lb	(b) (4), (b) (6)	11 Dec 2020 17:47:46
DataPoint set to visible.	System	11 Dec 2020 17:46:42

US3632127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:03:00
User entered '98.7' F	(b) (4), (b) (6)	11 Dec 2020 17:47:46

US3632127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:03:00
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Dec 2020 17:47:46

US3632127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:03:00
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:47:46

US3632127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:03:00
User entered '78'	(b) (4), (b) (6)	11 Dec 2020 17:47:46

US3632127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Dec 2020 17:47:46

US3632127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:03:00
User entered '16'	(b) (4), (b) (6)	11 Dec 2020 17:47:46

US3632127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Dec 2020 17:47:46

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:03:00
User entered '129'	(b) (4), (b) (6)	11 Dec 2020 17:47:46

US3632127

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)
User entered 'mmHg'	System	11 Dec 2020 17:47:46

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:03:00
User entered '89'	(b) (4), (b) (6)	11 Dec 2020 17:47:46

US3632127

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)
User entered 'mmHg'	System	11 Dec 2020 17:47:46

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:03:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Dec 2020 17:47:54

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:03:43
User entered '11 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 17:47:54

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:03:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Dec 2020 17:48:00

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:03:55
User entered '11 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 17:48:00

US3632127

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:33:55
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:46:41

US3632127

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:33:55
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:46:41

US3632127

Folder: Convalescence Visit Day 28 (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)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:33:55
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:46:41

US3632127

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	04 Dec 2020 14:46:41

US3632127

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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:00:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Jan 2021 15:43:04

US3632127

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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:00:40
User entered '15 Jan 2021'	(b) (4), (b) (6)	15 Jan 2021 15:43:04

US3632127

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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:00:40
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	15 Jan 2021 15:43:04

US3632127

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)	25 Apr 2021 02:57:22
User entered 'UNBLND_DECIDE'	System	15 Jan 2021 15:43:04

US3632127

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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:01:12
User entered '15 Jan 2021'	(b) (4), (b) (6)	15 Jan 2021 15:43:25

US3632127

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)	25 Apr 2021 02:57:22
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:34:44
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:37:15
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:30:31
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:46:59

US3632127

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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:01:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Jan 2021 15:43:25

US3632127

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)	25 Apr 2021 02:57:22
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:34:44
User closed query 'Per CDA, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 16:18:55
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:37:15
Query 'Per CDA, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 12:30:35
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	09 Apr 2021 12:30:31
User opened query 'Per CDA, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 22:16:02
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:46:59

US3632127

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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:01:12
User entered '15 Jan 2021'	(b) (4), (b) (6)	15 Jan 2021 15:43:25

US3632127

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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:01:12
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	15 Jan 2021 15:43:25

US3632127

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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:01:12
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 09:56:48
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	15 Jan 2021 15:43:25

US3632127

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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:01:12
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 09:56:48
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	15 Jan 2021 15:43:25

US3632127

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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:01:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Jan 2021 15:43:25

US3632127

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)	25 Apr 2021 02:57:22
User entered '1'	System	15 Jan 2021 15:43:25

US3632127

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)	25 Apr 2021 02:57:22
User entered '1'	System	15 Jan 2021 15:43:25

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:01:37
User entered '65' in	(b) (4), (b) (6)	15 Jan 2021 16:58:52

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:01:39
User entered '247.4' lb	(b) (4), (b) (6)	15 Jan 2021 16:58:52

US3632127

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:08:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:57:22
User entered '41.25560'	System	15 Jan 2021 16:58:52
DataPoint set to visible.	System	15 Jan 2021 15:43:25

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:01:37
User entered '65' in	(b) (4), (b) (6)	15 Jan 2021 16:58:52

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:01:39
User entered '247.4' lb	(b) (4), (b) (6)	15 Jan 2021 16:58:52

US3632127

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:08:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:57:22
User entered '41.25560'	System	15 Jan 2021 16:58:52
DataPoint set to visible.	System	15 Jan 2021 15:43:25

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	15 Jan 2021 16:58:52

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:01:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Jan 2021 16:58:52

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:01:34
User entered '15 Jan 2021'	(b) (4), (b) (6)	15 Jan 2021 16:58:52

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:01:34
User entered '09:45'	(b) (4), (b) (6)	15 Jan 2021 16:58:52

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User entered '15 Jan 2021 09:45'	System	15 Jan 2021 16:58:52

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:01:34
User entered '97.4' F	(b) (4), (b) (6)	15 Jan 2021 16:58:52

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:01:34
User entered 'Oral (Oral)'	(b) (4), (b) (6)	15 Jan 2021 16:58:52

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:01:34
User entered empty.	(b) (4), (b) (6)	15 Jan 2021 16:58:52

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:01:34
User entered '84'	(b) (4), (b) (6)	15 Jan 2021 16:58:52

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User entered 'bpm'	System	15 Jan 2021 16:58:52

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:01:34
User entered '18'	(b) (4), (b) (6)	15 Jan 2021 16:58:52

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User entered 'breaths/min'	System	15 Jan 2021 16:58:52

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:01:34
User entered '116'	(b) (4), (b) (6)	15 Jan 2021 16:58:52

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User entered 'mmHg'	System	15 Jan 2021 16:58:52

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:01:34
User entered '80'	(b) (4), (b) (6)	15 Jan 2021 16:58:52

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User entered 'mmHg'	System	15 Jan 2021 16:58:52

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:01:37
User entered '65' in	(b) (4), (b) (6)	15 Jan 2021 16:58:52

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:01:39
User entered '247.4' lb	(b) (4), (b) (6)	15 Jan 2021 16:58:52

US3632127

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:08:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:57:22
User entered '41.25560'	System	15 Jan 2021 16:58:52
DataPoint set to visible.	System	15 Jan 2021 15:43:25

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	15 Jan 2021 16:58:52

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Jan 2021 16:58:52

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:17
User entered '15 Jan 2021'	(b) (4), (b) (6)	15 Jan 2021 16:58:52

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:17
User entered '11:56'	(b) (4), (b) (6)	15 Jan 2021 16:58:52

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User entered '15 Jan 2021 11:56'	System	15 Jan 2021 16:58:52

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 20:03:17
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)	18 Jan 2021 09:08:55
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' (Site from System).	(b) (4), (b) (6)	15 Jan 2021 16:59:08
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	15 Jan 2021 16:58:52
User entered '96.7' F	(b) (4), (b) (6)	15 Jan 2021 16:58:52

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:17
User entered 'Oral (Oral)'	(b) (4), (b) (6)	15 Jan 2021 16:58:52

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:17
User entered empty.	(b) (4), (b) (6)	15 Jan 2021 16:58:52

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:17
User entered '85'	(b) (4), (b) (6)	15 Jan 2021 16:58:52

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User entered 'bpm'	System	15 Jan 2021 16:58:52

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:17
User entered '18'	(b) (4), (b) (6)	15 Jan 2021 16:58:52

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User entered 'breaths/min'	System	15 Jan 2021 16:58:52

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:17
User entered '133'	(b) (4), (b) (6)	15 Jan 2021 16:58:52

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User entered 'mmHg'	System	15 Jan 2021 16:58:52

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:17
User entered '83'	(b) (4), (b) (6)	15 Jan 2021 16:58:52

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User entered 'mmHg'	System	15 Jan 2021 16:58:52

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Jan 2021 15:44:12

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:42
User entered '15 Jan 2021'	(b) (4), (b) (6)	15 Jan 2021 15:44:12

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Jan 2021 16:28:29

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:54
User entered empty.	(b) (4), (b) (6)	15 Jan 2021 16:28:29

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 20:03:54
User entered empty.	(b) (4), (b) (6)	15 Jan 2021 16:28:29

US3632127

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

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:57:22
User entered 'mRNA-1273'	System	15 Jan 2021 16:28:29
DataPoint set to visible.	System	15 Jan 2021 15:43:25

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:54
User entered '15 Jan 2021'	(b) (4), (b) (6)	15 Jan 2021 16:28:29

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:54
User entered '11:25'	(b) (4), (b) (6)	15 Jan 2021 16:28:29

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User entered '15 Jan 2021 11:25'	System	15 Jan 2021 16:28:29

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:54
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	15 Jan 2021 16:28:29

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 20:03:54
User entered 'ONCE'	System	15 Jan 2021 16:28:29

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User entered 'INTRAMUSCULAR'	System	15 Jan 2021 16:28:29

US3632127

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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:04:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Jan 2021 15:43:44

US3632127

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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:04:13
User entered '15 Jan 2021'	(b) (4), (b) (6)	15 Jan 2021 15:43:44

US3632127

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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:04:13
User entered '10:15'	(b) (4), (b) (6)	15 Jan 2021 15:43:44

US3632127

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)	25 Apr 2021 02:57:22
User entered '15 Jan 2021 10:15'	System	15 Jan 2021 15:43:44

US3632127

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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:04:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Jan 2021 15:43:54

US3632127

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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:04:39
User entered '15 Jan 2021'	(b) (4), (b) (6)	15 Jan 2021 15:43:54

US3632127

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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:04:39
User entered '10:12'	(b) (4), (b) (6)	15 Jan 2021 15:43:54

US3632127

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)	25 Apr 2021 02:57:22
User entered '15 Jan 2021 10:12'	System	15 Jan 2021 15:43:54

US3632127

Folder: Participant Decision Visit / OL-D1 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:04:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Jan 2021 15:43:58

US3632127

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

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:57:22
User entered '1'	System	15 Jan 2021 15:43:58

US3632127

Folder: Safety Call OL-D8 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:05:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 20:43:10

US3632127

Folder: Safety Call OL-D8 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:05:20
User entered '22 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 20:43:10

US3632127

Folder: Safety Call OL-D8 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:05:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Jan 2021 20:43:10

US3632127

Folder: Safety Call OL-D8 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:05:20
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 20:43:10

US3632127

Folder: Safety Call OL-D8 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:05:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 20:43:34

US3632127

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:57:22
User entered '1'	System	22 Jan 2021 20:43:34

US3632127

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:57:22
User entered '1'	System	22 Jan 2021 20:43:34
DataPoint set to visible.	System	22 Jan 2021 20:43:34

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:13:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Feb 2021 17:57:37

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:13:29
User entered '12 Feb 2021'	(b) (4), (b) (6)	12 Feb 2021 17:57:37

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:13:29
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	12 Feb 2021 17:57:37

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User entered 'OLD29'	System	12 Feb 2021 17:57:37

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	12 Feb 2021 18:01:42

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:15:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Feb 2021 18:01:42

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:15:37
User entered '12 Feb 2021'	(b) (4), (b) (6)	12 Feb 2021 18:01:42

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:15:37
User entered '10:24'	(b) (4), (b) (6)	12 Feb 2021 18:01:42

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User entered '12 Feb 2021 10:24'	System	12 Feb 2021 18:01:42

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:15:37
User entered '98.4' F	(b) (4), (b) (6)	12 Feb 2021 18:01:42

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:15:37
User entered 'Oral (Oral)'	(b) (4), (b) (6)	12 Feb 2021 18:01:42

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:15:37
User entered empty.	(b) (4), (b) (6)	12 Feb 2021 18:01:42

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:15:37
User entered '83'	(b) (4), (b) (6)	12 Feb 2021 18:01:42

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User entered 'bpm'	System	12 Feb 2021 18:01:42

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:15:37
User entered '16'	(b) (4), (b) (6)	12 Feb 2021 18:01:42

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User entered 'breaths/min'	System	12 Feb 2021 18:01:42

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:15:37
User entered '128'	(b) (4), (b) (6)	12 Feb 2021 18:01:42

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User entered 'mmHg'	System	12 Feb 2021 18:01:42

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:15:37
User entered '78'	(b) (4), (b) (6)	12 Feb 2021 18:01:42

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User entered 'mmHg'	System	12 Feb 2021 18:01:42

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	12 Feb 2021 18:01:42

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:19:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Feb 2021 18:01:42

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:19:04
User entered '12 Feb 2021'	(b) (4), (b) (6)	12 Feb 2021 18:01:42

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:19:04
User entered '12:11'	(b) (4), (b) (6)	12 Feb 2021 18:01:42

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User entered '12 Feb 2021 12:11'	System	12 Feb 2021 18:01:42

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:19:04
User entered '98.2' F	(b) (4), (b) (6)	12 Feb 2021 18:01:42

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:19:04
User entered 'Oral (Oral)'	(b) (4), (b) (6)	12 Feb 2021 18:01:42

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:19:04
User entered empty.	(b) (4), (b) (6)	12 Feb 2021 18:01:42

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:19:04
User entered '79'	(b) (4), (b) (6)	12 Feb 2021 18:01:42

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User entered 'bpm'	System	12 Feb 2021 18:01:42

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:19:04
User entered '18'	(b) (4), (b) (6)	12 Feb 2021 18:01:42

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User entered 'breaths/min'	System	12 Feb 2021 18:01:42

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:19:04
User entered '139'	(b) (4), (b) (6)	12 Feb 2021 18:01:42

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User entered 'mmHg'	System	12 Feb 2021 18:01:42

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:19:04
User entered '87'	(b) (4), (b) (6)	12 Feb 2021 18:01:42

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User entered 'mmHg'	System	12 Feb 2021 18:01:42

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:19:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Feb 2021 18:02:11

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:19:11
User entered '12 Feb 2021'	(b) (4), (b) (6)	12 Feb 2021 18:02:11

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:19:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Feb 2021 18:02:50

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:19:36
User entered empty.	(b) (4), (b) (6)	12 Feb 2021 18:02:50

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:19:36
User entered empty.	(b) (4), (b) (6)	12 Feb 2021 18:02:50

US3632127

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:57:22
User entered 'mRNA-1273'	System	12 Feb 2021 18:02:50
DataPoint set to visible.	System	22 Jan 2021 20:43:34

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:19:36
User entered '12 Feb 2021'	(b) (4), (b) (6)	12 Feb 2021 18:02:50

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:19:36
User entered '11:40'	(b) (4), (b) (6)	12 Feb 2021 18:02:50

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User entered '12 Feb 2021 11:40'	System	12 Feb 2021 18:02:50

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:19:36
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	12 Feb 2021 18:02:50

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 20:19:36
User entered 'ONCE'	System	12 Feb 2021 18:02:50

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User entered 'INTRAMUSCULAR'	System	12 Feb 2021 18:02:50

US3632127

Folder: OL-D29 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:19:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Feb 2021 18:03:02

US3632127

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:57:22
User entered '1'	System	12 Feb 2021 18:03:02

US3632127

Folder: Safety Call OL-D36 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:05:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Feb 2021 15:51:10

US3632127

Folder: Safety Call OL-D36 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:05:24
User entered '19 Feb 2021'	(b) (4), (b) (6)	25 Feb 2021 15:51:10

US3632127

Folder: Safety Call OL-D36 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:05:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	25 Feb 2021 15:51:10

US3632127

Folder: Safety Call OL-D36 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:05:24
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 15:51:10

US3632127

Folder: Safety Call OL-D36 (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)	25 Apr 2021 02:57:22
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:05:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Feb 2021 15:51:15

US3632127

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:57:22
User entered '1'	System	25 Feb 2021 15:51:15

US3632127

Folder: OL-D57 (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)	25 Apr 2021 02:57:22
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:04:24
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 20:13:26

US3632127

Folder: OL-D57 (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)	25 Apr 2021 02:57:22
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:04:24
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 20:13:26

US3632127

Folder: OL-D57 (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)	25 Apr 2021 02:57:22
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:04:24
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 20:13:26

US3632127

Folder: OL-D57 (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)	25 Apr 2021 02:57:22
User entered 'OLD57'	System	12 Mar 2021 20:13:26

US3632127

Folder: OL-D57 (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)	25 Apr 2021 02:57:22
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:05:20
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 20:16:39

US3632127

Folder: OL-D57 (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)	25 Apr 2021 02:57:22
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:05:20
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 20:16:39

US3632127

Folder: OL-D57 (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)	25 Apr 2021 02:57:22
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:05:20
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 20:16:39

US3632127

Folder: OL-D57 (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)	25 Apr 2021 02:57:22
User entered empty.	System	12 Mar 2021 20:16:39

US3632127

Folder: OL-D57 (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)	25 Apr 2021 02:57:22
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:05:20
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 20:16:39

US3632127

Folder: OL-D57 (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)	25 Apr 2021 02:57:22
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:05:20
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 20:16:39

US3632127

Folder: OL-D57 (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)	25 Apr 2021 02:57:22
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:05:20
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 20:16:39

US3632127

Folder: OL-D57 (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)	25 Apr 2021 02:57:22
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:05:20
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 20:16:39

US3632127

Folder: OL-D57 (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)	25 Apr 2021 02:57:22
User entered empty.	System	12 Mar 2021 20:16:39

US3632127

Folder: OL-D57 (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)	25 Apr 2021 02:57:22
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:05:20
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 20:16:39

US3632127

Folder: OL-D57 (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)	25 Apr 2021 02:57:22
User entered empty.	System	12 Mar 2021 20:16:39

US3632127

Folder: OL-D57 (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)	25 Apr 2021 02:57:22
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:05:20
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 20:16:39

US3632127

Folder: OL-D57 (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)	25 Apr 2021 02:57:22
User entered empty.	System	12 Mar 2021 20:16:39

US3632127

Folder: OL-D57 (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)	25 Apr 2021 02:57:22
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:05:20
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 20:16:39

US3632127

Folder: OL-D57 (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)	25 Apr 2021 02:57:22
User entered empty.	System	12 Mar 2021 20:16:39

US3632127

Folder: OL-D57 (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)	25 Apr 2021 02:57:22

US3632127

Folder: OL-D57 (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)	25 Apr 2021 02:57:22

US3632127

Folder: OL-D57 (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)	25 Apr 2021 02:57:22
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:05:28
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 20:17:57

US3632127

Folder: OL-D57 (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)	25 Apr 2021 02:57:22
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:05:28
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 20:17:57

US3632127

Folder: OL-D57 (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)	25 Apr 2021 02:57:22
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:05:38
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 20:19:18

US3632127

Folder: OL-D57 (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)	25 Apr 2021 02:57:22
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:05:38
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 20:19:18

US3632127

Folder: OL-D57 (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)	25 Apr 2021 02:57:22
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:05:38
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
User entered '15:03'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 20:19:18

US3632127

Folder: OL-D57 (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)	25 Apr 2021 02:57:22
User entered '12 Mar 2021 15:03'	System	12 Mar 2021 20:19:18

US3632127

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)	04 May 2021 04:53:24
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:19:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 16:45:37

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4)	17 Nov 2020 17:19:20
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:05
User entered	(b) (4), (b) (6)	11 Nov 2020 20:57:02
'USA-US120-2020-mRNA-1273-P301000004'	System	11 Nov 2020 20:57:02
User entered 'New'	(b) (4), (b) (6)	11 Nov 2020 20:57:02

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:19:28
User coded data point as SOC: Social circumstances, HLT: Legal issues, HLT: Criminal activity, PT: Sexual abuse, LLT: Sexual assault - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 17:02:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 17:02:41
Data point term sent to Coder	System	10 Nov 2020 17:02:11
User entered 'sexual assault'	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:19:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:19:41
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

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.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:19:43
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:22:59
User entered '07 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:19:47
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	11 Nov 2020 14:01:52
User entered empty; reason for change New Information	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:01:52
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	11 Nov 2020 14:01:24
User entered '17:30' reason for change: New Information	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:01:24
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 14:01:52
User entered '07 Nov 2020 17:30'	System	11 Nov 2020 14:01:24
User entered empty.	System	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:19:49
User entered 'No (N)' reason for change: New Information	Christina Bacher (b) (4) (b) (4)	13 Nov 2020 15:43:54
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 14:01:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 14:01:24
User entered 'Yes (Y)' reason for change: New Information	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:01:24
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 17:01:41
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:19:51
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	13 Nov 2020 15:44:17
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	13 Nov 2020 15:44:17
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	13 Nov 2020 15:43:54
User entered '7 Nov 2020' reason for change: New Information	Christina Bacher (b) (4)	13 Nov 2020 15:43:54
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:19:53
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:19:56
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 14:01:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 14:01:24
User entered 'Grade 4 (Grade 4)' reason for change: New Information	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:01:24
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 17:01:41
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:19:58
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	11 Nov 2020 14:01:24
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	10 Nov 2020 17:01:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

Death

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:00
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:02
User entered '1' reason for change: New Information	Christina Bacher (b) (4)	11 Nov 2020 14:01:24
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:09
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:11
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:14
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:15
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:17
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:20
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:21
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:23
User entered '1' reason for change: Data Entry Error	Christina Bacher (b) (4)	11 Nov 2020 14:01:24
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:27
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:54
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:58
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 14:01:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 14:01:24
User entered 'None (NONE)' reason for change: New Information	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:01:24
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 17:01:41
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:48
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:49
User entered '1'	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 15:28:27
DataPoint Un-verified.	Catherine Abrams (b) (4) (b) (4)	19 Nov 2020 21:18:58
User entered '0' reason for change: Data Entry Error	Catherine Abrams (b) (4) (b) (4)	19 Nov 2020 21:18:58
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:21:53
User entered '1'	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:22:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Christina Bacher (b) (4) (b) (4)	13 Nov 2020 15:44:17
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 14:01:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 14:01:24
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: New Information	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:01:24
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 17:01:41
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

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.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:22:47
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User closed query 'PV Query: Please provide dates of HIV and STD lab testing including syphilis, gonorrhea, and chlamydia.' (Site from Safety).	(b) (4)	19 Jan 2021 17:49:57
Query 'PV Query: Please provide dates of HIV and STD lab testing including syphilis, gonorrhea, and chlamydia.' answered with 'Tests were done on 07NOV2020' (Site from Safety).	(b) (4), (b) (6)	15 Jan 2021 15:39:20
User opened query 'PV Query: Please provide dates of HIV and STD lab testing including syphilis, gonorrhea, and chlamydia.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 17:51:27
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 20:29:17
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is available.' answered with 'Subject was tested for HIV and STD including syphilis, gonorrhea, and chlamydia. All test results were negative' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 17:25:28
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	29 Nov 2020 11:40:34
User closed query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 16:03:01
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 16:02:59
Query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' answered with 'Participant was not tested for COVID-19' (Site from Safety).	Christina Bacher (b) (4)	24 Nov 2020 18:45:35

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'In process of obtaining records' (Site from Safety).	Christina Bacher (b) (4) (b) (4)	24 Nov 2020 18:45:22
User opened query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 16:29:36
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 16:28:37
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:22:50
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	11 Nov 2020 14:01:24
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	11 Nov 2020 14:01:24
User entered 'PARTICIPANT WAS A VICTIM OF SEXUAL ASSAULT.' reason for change: New Information	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:01:24
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	10 Nov 2020 17:01:41
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:01:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 17:01:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:40

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:40
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:16
User coded data point as SOC: Injury, poisoning and procedural complications, HLGHT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Foot fracture, LLT: Fractured toe - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 14:32:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 14:32:33
Data point term sent to Coder	System	11 Nov 2020 14:03:53
User entered 'FRACTURED, 4TH, RIGHT TOE.'	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

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Folder: Adverse Events

Form: Adverse Events (2)

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)	29 Apr 2021 11:59:40
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:25
User entered 'Yes (Y)'	Christina Bacher (b) (4)	11 Nov 2020 14:03:12
	(b) (4)	

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

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)	29 Apr 2021 11:59:40
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:27
User entered 'No (N)'	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

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)	29 Apr 2021 11:59:40
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:29
User entered 'No (N)'	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

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Folder: Adverse Events

Form: Adverse Events (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)	29 Apr 2021 11:59:40
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:31
User entered '7 Nov 2020'	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

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)	29 Apr 2021 11:59:40
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:32
User entered empty.	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

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)	29 Apr 2021 11:59:40
User entered empty.	System	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:44:24
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:45:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Jan 2021 15:45:32
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:23:34
User entered 'Yes (Y)'	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

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Folder: Adverse Events

Form: Adverse Events (2)

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)	29 Apr 2021 11:59:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:41:44
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	15 Jan 2021 15:45:44
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	15 Jan 2021 15:45:44
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	15 Jan 2021 15:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	15 Jan 2021 15:45:32
User entered '15 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Jan 2021 15:45:32
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:23:37
User entered empty.	Christina Bacher (b) (4)	11 Nov 2020 14:03:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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)	29 Apr 2021 11:59:40
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:39
User entered empty.	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

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)	29 Apr 2021 11:59:40
User entered empty.	System	11 Nov 2020 14:03:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:40
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:41
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:40
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:43
User entered 'No (N)'	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:40
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:44
User entered '0'	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:40
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:47
User entered '0'	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

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)	29 Apr 2021 11:59:40
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:49
User entered '0'	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

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)	29 Apr 2021 11:59:40
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:51
User entered empty.	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

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)	29 Apr 2021 11:59:40
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:53
User entered empty.	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:40
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:54
User entered empty.	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:40
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:56
User entered empty.	Christina Bacher (b) (4)	11 Nov 2020 14:03:12
	(b) (4)	

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

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)	29 Apr 2021 11:59:40
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:57
User entered '0'	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:40
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:24:00
User entered '0'	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:40
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:24:03
User entered '0'	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:40
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:24:05
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 14:03:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 14:03:43
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:43
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 14:03:12
User entered empty.	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:40
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:24:07
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 14:03:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 14:03:43
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:43
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 14:03:12
User entered empty.	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:40
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:24:10
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 14:03:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 14:03:43
User entered 'None (NONE)' reason for change: Data Entry Error	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:43
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 14:03:12
User entered empty.	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:40
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:35:02
User closed query 'Per source, other actions taken include Medication. Please verify with source and update EDC accordingly.' (Site from CRA). Query 'Per source, other actions taken include Medication. Please verify with source and update EDC accordingly.' answered with 'Naproxen ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 21:35:00
User entered '0' reason for change: Per Query Resolution	Catherine Abrams (b) (4)	19 Nov 2020 21:14:39
User opened query 'Per source, other actions taken include Medication. Please verify with source and update EDC accordingly.' (Site from CRA). User entered '1'	(b) (4) Catherine Abrams (b) (4)	19 Nov 2020 21:13:40
	(b) (4), (b) (6)	17 Nov 2020 17:24:36
	Christina Bacher (b) (4)	11 Nov 2020 14:03:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:40
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:35:04
User entered '1' reason for change: Per Query Resolution	Catherine Abrams (b) (4)	19 Nov 2020 21:13:40
User entered '0'	(b) (4) Christina Bacher (b) (4)	11 Nov 2020 14:03:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:40
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:24:39
User entered '0'	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:44:35
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:45:44
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Jan 2021 15:45:44
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:24:42
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

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Folder: Adverse Events

Form: Adverse Events (2)

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)	29 Apr 2021 11:59:40
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:24:46
User entered empty.	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:40
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:24:47
User entered 'FRACTURE OCCURED DURING THE SEXUAL ASSAULT' reason for change: Data Entry Error	Christina Bacher (b) (4)	11 Nov 2020 14:03:43
User entered 'FRACTURE OCCURED DURING THE SEXUAL ASSUALT.'	Christina Bacher (b) (4)	11 Nov 2020 14:03:12

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Folder: Adverse Events

Form: Adverse Events (2)

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)	29 Apr 2021 11:59:40
User entered '0'	System	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

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)	29 Apr 2021 11:59:40
User entered '1'	System	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

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)	29 Apr 2021 11:59:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:45:49
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Cramp - version MedDRA\23.0.	Coder Import (b) (4)	11 Dec 2020 14:27:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Dec 2020 14:27:47
Data point term sent to Coder	System	11 Dec 2020 14:27:37
User entered 'Cramping'	Isaac Perez (b) (4)	11 Dec 2020 14:26:42

US3632127

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 locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:45:49
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered 'Yes (Y)'	(b) (4) Isaac Perez (b) (4) (b) (4)	11 Dec 2020 14:26:42

US3632127

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 locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:45:49
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered 'No (N)'	(b) (4) Isaac Perez (b) (4) (b) (4)	11 Dec 2020 14:26:42

US3632127

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 locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:45:49
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered 'No (N)'	(b) (4) Isaac Perez (b) (4) (b) (4)	11 Dec 2020 14:26:42

US3632127

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 locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:45:49
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered '6 Dec 2020'	(b) (4) Isaac Perez (b) (4) (b) (4)	11 Dec 2020 14:26:42

US3632127

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 locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:45:49
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered empty.	(b) (4) Isaac Perez (b) (4) (b) (4)	11 Dec 2020 14:26:42

US3632127

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 locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44
User entered empty.	System	11 Dec 2020 14:26:42

US3632127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:45:49
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered 'No (N)'	(b) (4) Isaac Perez (b) (4) (b) (4)	11 Dec 2020 14:26:42

US3632127

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 locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:45:49
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered '6 Dec 2020'	(b) (4) Isaac Perez (b) (4) (b) (4)	11 Dec 2020 14:26:42

US3632127

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 locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:45:49
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered empty.	(b) (4) Isaac Perez (b) (4) (b) (4)	11 Dec 2020 14:26:42

US3632127

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 locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44
User entered empty.	System	11 Dec 2020 14:26:42

US3632127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:45:49
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Isaac Perez (b) (4) (b) (4)	11 Dec 2020 14:26:42

US3632127

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 locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:45:49
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered 'No (N)'	(b) (4) Isaac Perez (b) (4) (b) (4)	11 Dec 2020 14:26:42

US3632127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:45:49
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered '0'	(b) (4) Isaac Perez (b) (4) (b) (4)	11 Dec 2020 14:26:42

US3632127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:45:49
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered '0'	(b) (4) Isaac Perez (b) (4) (b) (4)	11 Dec 2020 14:26:42

US3632127

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 locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:45:49
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered '0'	(b) (4) Isaac Perez (b) (4) (b) (4)	11 Dec 2020 14:26:42

US3632127

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 locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:45:49
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered empty.	(b) (4) Isaac Perez (b) (4) (b) (4)	11 Dec 2020 14:26:42

US3632127

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 locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:45:49
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered empty.	(b) (4) Isaac Perez (b) (4) (b) (4)	11 Dec 2020 14:26:42

US3632127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:45:49
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered empty.	(b) (4) Isaac Perez (b) (4) (b) (4)	11 Dec 2020 14:26:42

US3632127

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 locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:45:49
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered empty.	(b) (4) Isaac Perez (b) (4) (b) (4)	11 Dec 2020 14:26:42

US3632127

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 locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:45:49
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered '0'	(b) (4) Isaac Perez (b) (4) (b) (4)	11 Dec 2020 14:26:42

US3632127

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 locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:45:49
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered '0'	(b) (4) Isaac Perez (b) (4) (b) (4)	11 Dec 2020 14:26:42

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Folder: Adverse Events

Form: Adverse Events (3)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:45:49
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered '0'	(b) (4) Isaac Perez (b) (4) (b) (4)	11 Dec 2020 14:26:42

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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 locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:45:49
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered 'Not Related (NOT RELATED)'	(b) (4) Isaac Perez (b) (4) (b) (4)	11 Dec 2020 14:26:42

US3632127

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 locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:45:49
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered 'Not Related (NOT RELATED)'	(b) (4) Isaac Perez (b) (4) (b) (4)	11 Dec 2020 14:26:42

US3632127

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 locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:45:49
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	15 Mar 2021 12:27:39
User entered 'Not Applicable (NOT APPLICABLE)'	Isaac Perez (b) (4) (b) (4)	11 Dec 2020 14:26:42

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:45:49
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered '1'	(b) (4) Isaac Perez (b) (4) (b) (4)	11 Dec 2020 14:26:42

US3632127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:45:49
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered '0'	(b) (4) Isaac Perez (b) (4) (b) (4)	11 Dec 2020 14:26:42

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:45:49
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered '0'	(b) (4) Isaac Perez (b) (4) (b) (4)	11 Dec 2020 14:26:42

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:45:49
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
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	11 Dec 2020 14:26:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	System	11 Dec 2020 14:26:48
Data Entry Error	Isaac Perez (b) (4)	11 Dec 2020 14:26:48
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	11 Dec 2020 14:26:42
	Isaac Perez (b) (4)	11 Dec 2020 14:26:42
	(b) (4)	

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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 locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:45:49
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered empty.	(b) (4) Isaac Perez (b) (4) (b) (4)	11 Dec 2020 14:26:42

US3632127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:08:05

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:45:49
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User closed query 'Per DM CLR: Note, SAE Narrative = recieved an IV. Please review if this should be recorded in CM and update Other Action field to reflect this given medication. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 16:10:58
Query 'Per DM CLR: Note, SAE Narrative = recieved an IV. Please review if this should be recorded in CM and update Other Action field to reflect this given medication. Else, clarify. ' answered with 'only received IV fluids (unknown which ones to participant)' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 14:19:56
User opened query 'Per DM CLR: Note, SAE Narrative = recieved an IV. Please review if this should be recorded in CM and update Other Action field to reflect this given medication. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 04:07:04
User entered 'PARTICIPANT EXPERIENCED SEVERE CRAMPING on upper thighs and lower abdomen AND CALLED EMS due to concern for cardiac event. UPON ARRIVAL, PARTICIPANT DID NOT CONSENT TO A VISIT TO THE ER, BUT WAS TREATED BY EMTS AT SITE. AFTER RECEIVING AN IV, PARTICIPANT'S CRAMPING RESOLVED.' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 17:26:48
User entered 'Participant experienced severe cramping and called EMS. Upon arrival, participant did not consent to a visit to the ER, but was treated by EMTs at site. After receiving an IV, participant's cramping resolved.'	Isaac Perez (b) (4) (b) (4)	11 Dec 2020 14:26:42

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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 locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44
User entered '0'	System	11 Dec 2020 14:26:42

US3632127

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 locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44
User entered '1'	System	11 Dec 2020 14:26:42

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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 locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:44

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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)	29 Apr 2021 11:59:50

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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)	29 Apr 2021 11:59:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:46:58
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
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)	19 Feb 2021 04:44:18
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'No, illness visit was not completed. A protocol deviation has been written and put into source and on the PD log. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 19:54:24
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 11:25:29
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Jan 2021 15:48:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Jan 2021 15:48:53
Data point term sent to Coder System	System	15 Jan 2021 15:48:06
User entered 'Intermittent cough'	(b) (4), (b) (6)	15 Jan 2021 15:47:10

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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)	29 Apr 2021 11:59:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:46:58
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:47:10

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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)	29 Apr 2021 11:59:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:46:58
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:47:10

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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)	29 Apr 2021 11:59:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:46:58
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:47:10

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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)	29 Apr 2021 11:59:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:46:58
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered '3 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:47:10

US3632127

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)	29 Apr 2021 11:59:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:46:58
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:47:10

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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)	29 Apr 2021 11:59:50
User entered empty.	System	15 Jan 2021 15:47:10

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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)	29 Apr 2021 11:59:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:46:58
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:47:10

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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)	29 Apr 2021 11:59:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:46:58
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:47:10

US3632127

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)	29 Apr 2021 11:59:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:46:58
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:47:10

US3632127

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)	29 Apr 2021 11:59:50
User entered empty.	System	15 Jan 2021 15:47:10

US3632127

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)	29 Apr 2021 11:59:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:46:58
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:47:10

US3632127

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)	29 Apr 2021 11:59:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:46:58
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:47:10

US3632127

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)	29 Apr 2021 11:59:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:46:58
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:47:10

US3632127

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)	29 Apr 2021 11:59:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:46:58
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:47:10

US3632127

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)	29 Apr 2021 11:59:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:46:58
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:47:10

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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)	29 Apr 2021 11:59:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:46:58
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:47:10

US3632127

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)	29 Apr 2021 11:59:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:46:58
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:47:10

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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)	29 Apr 2021 11:59:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:46:58
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:47:10

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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)	29 Apr 2021 11:59:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:46:58
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:47:10

US3632127

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)	29 Apr 2021 11:59:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:46:58
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:47:10

US3632127

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)	29 Apr 2021 11:59:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:46:58
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:47:10

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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)	29 Apr 2021 11:59:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:46:58
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:47:10

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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)	29 Apr 2021 11:59:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:46:58
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:47:10

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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)	29 Apr 2021 11:59:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:46:58
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:47:10

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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)	29 Apr 2021 11:59:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:46:58
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Jan 2021 15:47:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Jan 2021 15:47:20
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Jan 2021 15:47:20
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Jan 2021 15:47:10
User entered empty.	(b) (4), (b) (6)	15 Jan 2021 15:47:10

US3632127

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)	29 Apr 2021 11:59:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:46:58
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered 'l'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:47:10

US3632127

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)	29 Apr 2021 11:59:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:46:58
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:47:10

US3632127

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)	29 Apr 2021 11:59:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:46:58
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:47:10

US3632127

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)	29 Apr 2021 11:59:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:46:58
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:47:10

US3632127

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)	29 Apr 2021 11:59:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:46:58
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:47:10

US3632127

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)	29 Apr 2021 11:59:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:46:58
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:47:10

US3632127

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)	29 Apr 2021 11:59:50
User entered '0'	System	15 Jan 2021 15:47:10

US3632127

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)	29 Apr 2021 11:59:50
User entered '0'	System	15 Jan 2021 15:47:10

US3632127

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)	29 Apr 2021 11:59:50

US3632127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:55

US3632127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:48:07
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User coded data point as SOC: Infections and infestations, HLG: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\23.0.	Coder Import (b) (4)	25 Feb 2021 14:21:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Feb 2021 14:21:53
Data point term sent to Coder	System	25 Feb 2021 14:21:11
User entered 'Urinary Tract Infection'	(b) (4), (b) (6)	25 Feb 2021 14:20:49

US3632127

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)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:48:07
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:20:49

US3632127

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)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:48:07
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:20:49

US3632127

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)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:48:07
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:20:49

US3632127

Folder: Adverse Events

Form: Adverse Events (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)	29 Apr 2021 11:59:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:48:07
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:20:49

US3632127

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)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:48:07
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:20:49

US3632127

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)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:55
User entered empty.	System	25 Feb 2021 14:20:49

US3632127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:48:07
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered 'No (N)' reason for change: New Information	(b) (4) Sarah Wiatrek (b) (4)	11 Mar 2021 14:16:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Feb 2021 14:20:49

US3632127

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)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:48:07
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) System	11 Mar 2021 14:16:48
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	11 Mar 2021 14:16:48
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	11 Mar 2021 14:16:29
User entered '03 Mar 2021' reason for change: New Information	Sarah Wiatrek (b) (4)	11 Mar 2021 14:16:29
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 14:20:49

US3632127

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)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:48:07
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:20:49

US3632127

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)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:55
User entered empty.	System	25 Feb 2021 14:20:49

US3632127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:48:07
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:20:49

US3632127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:48:07
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:20:49

US3632127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:48:07
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:20:49

US3632127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:48:07
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:20:49

US3632127

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)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:48:07
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:20:49

US3632127

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)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:48:07
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:20:49

US3632127

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)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:48:07
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:20:49

US3632127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:48:07
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:20:49

US3632127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:48:07
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:20:49

US3632127

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)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:48:07
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:20:49

US3632127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:48:07
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:20:49

US3632127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:48:07
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:20:49

US3632127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:48:07
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:20:49

US3632127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:48:07
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:20:49

US3632127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:48:07
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:20:49

US3632127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:48:07
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:20:49

US3632127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:48:07
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered '1'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:20:49

US3632127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:48:07
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:20:49

US3632127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:26:56
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 18:48:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:48:07
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	15 Mar 2021 12:27:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Sarah Wiatrek (b) (4) (b) (4)	11 Mar 2021 14:16:48
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	25 Feb 2021 14:20:49

US3632127

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)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:48:07
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:20:49

US3632127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:08:05

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:48:07
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:27:39
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:20:49

US3632127

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)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:55
User entered '0'	System	25 Feb 2021 14:20:49

US3632127

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)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:55
User entered '1'	System	25 Feb 2021 14:20:49

US3632127

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)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:59:55

US3632127

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)	04 May 2021 04:59:36
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User closed query 'According to AE page, a concomitant procedure was completed. Please complete the Concomitant Procedures page in EDC.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:52:59
User closed query 'Source lists subject as taking Naproxen ongoing, with a start date of 07Nov2020. This is missing from EDC ConMed list. Please add medication to EDC.' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 16:52:54
Query 'Source lists subject as taking Naproxen ongoing, with a start date of 07Nov2020. This is missing from EDC ConMed list. Please add medication to EDC.' answered with 'updated' (Site from CRA).	Christina Bacher (b) (4) (b) (4)	20 Nov 2020 14:55:14
Query 'According to AE page, a concomitant procedure was completed. Please complete the Concomitant Procedures page in EDC.' answered with 'updated' (Site from CRA).	Catherine Abrams (b) (4) (b) (4)	19 Nov 2020 21:21:43
User opened query 'According to AE page, a concomitant procedure was completed. Please complete the Concomitant Procedures page in EDC.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 15:31:00
User opened query 'Source lists subject as taking Naproxen ongoing, with a start date of 07Nov2020. This is missing from EDC ConMed list. Please add medication to EDC.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 18:14:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:26:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:46:45

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:28:28
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, COMBINATIONS, ATC: ACE INHIBITORS AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE; LISINOPRIL, PRODUCTSYNONYM: LISINOPRIL HCTZ - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:52:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:52:17
Data point term sent to Coder User entered 'Lisinopril HCTZ'	System (b) (4), (b) (6)	13 Oct 2020 20:51:40 13 Oct 2020 20:51:02

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:28:40
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:51:02

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:29:53
User entered 'Hypertension'	(b) (4), (b) (6)	13 Oct 2020 20:51:02

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:29:55
User entered '10/12.5'	(b) (4), (b) (6)	13 Oct 2020 20:51:02

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:30:00
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 12:36:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 12:36:44
User entered 'mg (mg)' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	14 Oct 2020 12:36:44
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 20:51:02
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:51:02

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:30:02
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:51:02

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:30:05
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Oct 2020 20:51:02

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:30:07
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:51:02

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:30:09
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 20:51:02

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:30:10
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:51:02

US3632127

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)	19 Apr 2021 17:28:17
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 23:22:36
User entered '01 UNK 2010' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 23:22:36
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:31:31
User entered '1 UNK 2010'	(b) (4), (b) (6)	13 Oct 2020 20:51:02

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:31:39
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:51:02

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:31:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:51:02

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4)	17 Nov 2020 17:31:52
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 17:31:50
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:31:47
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:51:02

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:32:05
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:51:02

US3632127

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 '1'	System	13 Oct 2020 20:51:02

US3632127

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	13 Oct 2020 20:51:02

US3632127

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	13 Oct 2020 20:51:02

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:33:05
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 21:05:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 21:05:29
Data point term sent to Coder	System	13 Oct 2020 20:51:40
User entered 'Fish Oils'	(b) (4), (b) (6)	13 Oct 2020 20:51:29

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:33:18
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:51:29

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:33:20
User entered 'Hypertension'	(b) (4), (b) (6)	13 Oct 2020 20:51:29

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:33:22
User entered '360'	(b) (4), (b) (6)	13 Oct 2020 20:51:29

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:33:23
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 20:51:29

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:33:25
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:51:29

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:33:27
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Oct 2020 20:51:29

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:33:29
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:51:29

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:33:32
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 20:51:29

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:33:35
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:51:29

US3632127

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)	19 Apr 2021 17:28:41
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 23:22:49
User entered '01 UNK 2010' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 23:22:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:33:37
User entered '1 UNK 2010'	(b) (4), (b) (6)	13 Oct 2020 20:51:29

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:33:39
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:51:29

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:33:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:51:29

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:33:44
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:51:29

US3632127

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)	19 Apr 2021 17:28:52
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:51:29

US3632127

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 '1'	System	13 Oct 2020 20:51:29

US3632127

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	13 Oct 2020 20:51:29

US3632127

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	13 Oct 2020 20:51:29

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Dec 2020 13:46:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Dec 2020 13:46:44
Data point term sent to Coder Coding entries removed.	System Isaac Perez (b) (4)	07 Dec 2020 13:46:10 07 Dec 2020 13:45:15
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Dec 2020 13:36:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Dec 2020 13:36:50
Data point term sent to Coder Coding entries removed.	System Christina Bacher (b) (4)	01 Dec 2020 13:35:26 01 Dec 2020 13:34:35
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:33:57

US3632127

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)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:53:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:53:33
Data point term sent to Coder	System	13 Oct 2020 20:52:41
User entered 'Aspirin'	(b) (4), (b) (6)	13 Oct 2020 20:51:53

US3632127

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)	19 Apr 2021 17:29:04
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Un-verified.	(b) (4)	
	Isaac Perez (b) (4)	07 Dec 2020 13:45:15
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Isaac Perez (b) (4)	07 Dec 2020 13:45:15
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:33:59
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:51:53

US3632127

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)	19 Apr 2021 18:16:06
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User closed query 'Per CDM Re-Query. Please complete the indication as to what the prevention is for. Thank you' (Site from DM).	(b) (4)	
Query 'Per CDM Re-Query. Please complete the indication as to what the prevention is for. Thank you' answered with 'Updated indication and prophylaxis' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 08:38:46
Query 'Per CDM Re-Query. Please complete the indication as to what the prevention is for. Thank you' answered with 'Updated indication and prophylaxis' (Site from DM).	Isaac Perez (b) (4)	07 Dec 2020 13:45:26
User entered 'Heart Attack Prevention' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per CDM Re-Query. Please complete the indication as to what the prevention is for. Thank you' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 16:53:21
User closed query 'Per DM CLR: Please review Indication and please note, this medication is not typically used as treatment for the recorded condition. Please review and update indication as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 16:53:21
Query 'Per DM CLR: Please review Indication and please note, this medication is not typically used as treatment for the recorded condition. Please review and update indication as appropriate or provide clarification. ' answered with 'updated' (Site from DM).	Christina Bacher (b) (4)	01 Dec 2020 13:34:40
DataPoint Un-verified.	(b) (4)	
User entered 'prevention' reason for change: Data Entry Error	Christina Bacher (b) (4)	01 Dec 2020 13:34:35
User opened query 'Per DM CLR: Please review Indication and please note, this medication is not typically used as treatment for the recorded condition. Please review and update indication as appropriate or provide clarification. ' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please review Indication and please note, this medication is not typically used as treatment for the recorded condition. Please review and update indication as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 18:35:58
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:34:16
User entered 'Hypertension'	(b) (4), (b) (6)	13 Oct 2020 20:51:53

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:34:43
User entered '81'	(b) (4), (b) (6)	13 Oct 2020 20:51:53

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:34:45
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 20:51:53

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:34:47
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:51:53

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:34:49
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Oct 2020 20:51:53

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:34:51
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:51:53

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:34:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 20:51:53

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:34:55
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:51:53

US3632127

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)	19 Apr 2021 17:30:18
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 23:23:01
User entered '01 UNK 2010' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 23:23:01
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:34:57
User entered '1 UNK 2010'	(b) (4), (b) (6)	13 Oct 2020 20:51:53

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:35:07
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:51:53

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:35:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:51:53

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:35:11
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:51:53

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:35:17
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:51:53

US3632127

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	13 Oct 2020 20:51:53

US3632127

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	13 Oct 2020 20:51:53

US3632127

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	13 Oct 2020 20:51:53

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:35:22
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CURCUMA LONGA, PRODUCTSYNONYM: TURMERIC [CURCUMA LONGA] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 19:25:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 19:25:00
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: HERBAL ANTIINFLAMMATORY AND ANTIRHEUMATIC REMEDIES, PRODUCT: CURCUMA LONGA, PRODUCTSYNONYM: TURMERIC [CURCUMA LONGA] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 13:04:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 13:04:36
Data point term sent to Coder User entered 'Turmeric'	System (b) (4), (b) (6)	13 Oct 2020 20:52:45 13 Oct 2020 20:52:26

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:35:25
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:52:26

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:35:37
User entered 'Osteoarthritis'	(b) (4), (b) (6)	13 Oct 2020 20:52:26

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:39:08
User entered '538'	(b) (4), (b) (6)	13 Oct 2020 20:52:26

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:39:11
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 20:52:26

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:39:19
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:52:26

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:39:23
User entered 'twice daily (BID)'	(b) (4), (b) (6)	13 Oct 2020 20:52:26

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:39:41
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:52:26

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:39:56
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 20:52:26

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:40:00
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:52:26

US3632127

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)	19 Apr 2021 17:30:28
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 23:23:10
User entered '01 UNK 2010' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 23:23:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:40:10
User entered '1 UNK 2010'	(b) (4), (b) (6)	13 Oct 2020 20:52:26

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:40:25
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:52:26

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:40:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:52:26

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:42:51
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:52:26

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:42:53
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:52:26

US3632127

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 '2'	System	13 Oct 2020 20:52:26

US3632127

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	13 Oct 2020 20:52:26

US3632127

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	13 Oct 2020 20:52:26

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
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: NAPROXEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	31 Mar 2021 10:32:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	31 Mar 2021 10:32:30
Data point term sent to Coder Coding entries removed.	System Sarah Wiatrek (b) (4)	30 Mar 2021 17:54:37 30 Mar 2021 17:53:46
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:45:12
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: NAPROXEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Oct 2020 08:47:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Oct 2020 08:47:27
Data point term sent to Coder User entered 'Naproxen Oral Suspension'	System (b) (4), (b) (6)	13 Oct 2020 20:53:49 13 Oct 2020 20:53:03

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:45:14
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:53:03

US3632127

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)	19 Apr 2021 17:31:31
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	05 Apr 2021 01:17:38
DataPoint Un-verified.	Sarah Wiatrek (b) (4) (b) (4)	30 Mar 2021 17:53:46
User entered 'OSTEOARTHRITIS & Rheumatoid Arthritis' reason for change: Data Entry Error	Sarah Wiatrek (b) (4) (b) (4)	30 Mar 2021 17:53:46
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:45:18
User entered 'Osteoarthritis'	(b) (4), (b) (6)	13 Oct 2020 20:53:03

US3632127

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)	19 Apr 2021 17:31:36
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 10:34:07
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'updated' (Site from DM).	Christina Bacher (b) (4) (b) (4)	01 Dec 2020 13:36:44
DataPoint Un-verified.	Christina Bacher (b) (4) (b) (4)	01 Dec 2020 13:36:31
User entered '125' reason for change: Per Query Resolution	Christina Bacher (b) (4) (b) (4)	01 Dec 2020 13:36:31
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 18:36:20
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:45:27
User entered '1.25/5'	(b) (4), (b) (6)	13 Oct 2020 20:53:03

US3632127

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)	19 Apr 2021 17:31:46
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:37:15
Signature has been broken.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:23:02
User entered 'mg (mg)' reason for change: Per Query Resolution	(b) (4), (b) (6)	08 Apr 2021 14:23:02
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	(b) (4) System	01 Dec 2020 13:36:53
DataPoint Un-verified.	Christina Bacher (b) (4)	01 Dec 2020 13:36:53
User entered 'Other (OTHER)' reason for change: Per Query Resolution	(b) (4) Christina Bacher (b) (4)	01 Dec 2020 13:36:53
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	(b) (4) System	01 Dec 2020 13:36:31
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:45:30
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 20:53:03

US3632127

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)	19 Apr 2021 17:31:53
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:37:15
User closed query 'Per CDM: Please note that "mg" is one of the available options in the drop-down list provided for Dose unit. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 11:50:06
Query 'Per CDM: Please note that "mg" is one of the available options in the drop-down list provided for Dose unit. Review and update as appropriate. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 14:23:26
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 14:23:02
User closed query 'Per DM CLR: Please remove extraneous data and ensure that only the actual unit is captured in this field (dose=125, unit=mg). Note that dose in MG is acceptable. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 08:47:23
User opened query 'Per CDM: Please note that "mg" is one of the available options in the drop-down list provided for Dose unit. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 08:47:22
Query 'Per DM CLR: Please remove extraneous data and ensure that only the actual unit is captured in this field (dose=125, unit=mg). Note that dose in MG is acceptable. Update as appropriate. ' answered with 'completed ' (Site from DM).	Aastha KC (b) (4)	07 Apr 2021 17:17:45
Signature has been broken.	Aastha KC (b) (4)	07 Apr 2021 17:17:16
User entered 'MG' reason for change: Data Entry Error	Aastha KC (b) (4)	07 Apr 2021 17:17:16
User opened query 'Per DM CLR: Please remove extraneous data and ensure that only the actual unit is captured in this field (dose=125, unit=mg). Note that dose in MG is acceptable. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 11:35:00
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Un-verified.	Christina Bacher (b) (4)	01 Dec 2020 13:36:31

US3632127

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)
User entered '125 mg/ 5 mL' reason for change:	Christina Bacher (b) (4)	01 Dec 2020 13:36:31
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:48:00
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:53:03

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:48:02
User entered 'as needed (PRN)'	(b) (4), (b) (6)	13 Oct 2020 20:53:03

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:48:05
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:53:03

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:48:10
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 20:53:03

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:48:12
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:53:03

US3632127

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)	19 Apr 2021 17:32:00
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 23:23:22
User entered '01 UNK 2005' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 23:23:22
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:48:15
User entered '1 UNK 2005'	(b) (4), (b) (6)	13 Oct 2020 20:53:03

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:48:16
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:53:03

US3632127

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)	19 Apr 2021 17:32:05
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
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	14 Oct 2020 12:37:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelly Likos (b) (4)	14 Oct 2020 12:37:02
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	13 Oct 2020 20:53:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:53:38
	(b) (4), (b) (6)	13 Oct 2020 20:53:03

US3632127

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)	19 Apr 2021 17:32:07
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:53:03

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:50:00
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:53:03

US3632127

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	13 Oct 2020 20:53:03

US3632127

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	13 Oct 2020 20:53:03

US3632127

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	13 Oct 2020 20:53:03

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:51:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), COMBINATIONS, PRODUCT: ASCORBIC ACID; ROSA CANINA; SODIUM ASCORBATE, PRODUCTS YNONYM: POWER C - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 05:29:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 05:29:30
Data point term sent to Coder	System	13 Oct 2020 20:54:51
User entered 'Power C Gummies'	(b) (4), (b) (6)	13 Oct 2020 20:54:32

US3632127

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)	19 Apr 2021 17:32:26
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:44:08
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'Taken as a prophylaxis for general health. Updated to 'Yes'.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 18:51:53
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 18:51:40
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 18:51:40
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 18:36:37
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:51:59
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:54:32

US3632127

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)	19 Apr 2021 17:37:25
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 17:37:07
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:52:10
User entered 'General Health'	(b) (4), (b) (6)	13 Oct 2020 20:54:32

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:52:13
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 12:52:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 12:52:03
User entered '2' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	14 Oct 2020 12:52:03
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 20:54:32
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:54:32

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:52:18
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 12:52:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 12:52:03
User entered 'Other (OTHER)' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	14 Oct 2020 12:52:03
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 20:54:32
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:54:32

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:52:19
User entered 'gummies' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	14 Oct 2020 12:52:03
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:54:32

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:52:21
User entered 'twice daily (BID)'	(b) (4), (b) (6)	13 Oct 2020 20:54:32

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:52:23
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:54:32

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:52:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 20:54:32

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:52:31
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:54:32

US3632127

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)	19 Apr 2021 17:37:35
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 23:23:31
User entered '01 Feb 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 23:23:31
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:52:50
User entered '1 Feb 2020'	(b) (4), (b) (6)	13 Oct 2020 20:54:32

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:53:14
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:54:32

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:53:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:54:32

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:53:25
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:54:32

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:53:27
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:54:32

US3632127

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 '2'	System	13 Oct 2020 20:54:32

US3632127

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 '1'	System	13 Oct 2020 20:54:32

US3632127

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 '804 (804)'	System	13 Oct 2020 20:54:32

US3632127

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 signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:53:35
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: HERBAL ANTIINFLAMMATORY AND ANTIRHEUMATIC REMEDIES, PRODUCT: VACCINIUM MACROCARPON, PRODUCTSYNONYM: CRANBERRY [VACCINIUM MACROCARPON] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:56:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:56:28
Data point term sent to Coder	System	13 Oct 2020 20:55:52
User entered 'Cranberry'	(b) (4), (b) (6)	13 Oct 2020 20:55:00

US3632127

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)	19 Apr 2021 17:37:59
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:44:27
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'Taken as a prophylaxis for general health. Updated to 'Yes'.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 18:52:05
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 18:51:59
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 18:51:59
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 18:36:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:53:39
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:55:00

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:53:41
User entered 'General Health'	(b) (4), (b) (6)	13 Oct 2020 20:55:00

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:53:46
User entered '4200'	(b) (4), (b) (6)	13 Oct 2020 20:55:00

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:53:49
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 20:55:00

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:53:51
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:55:00

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:53:53
User entered 'twice daily (BID)'	(b) (4), (b) (6)	13 Oct 2020 20:55:00

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:53:54
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:55:00

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:53:56
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 20:55:00

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:53:58
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:55:00

US3632127

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)	19 Apr 2021 17:38:26
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 23:23:42
User entered '01 UNK 2005' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 23:23:42
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:54:02
User entered '1 UNK 2005'	(b) (4), (b) (6)	13 Oct 2020 20:55:00

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:54:06
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:55:00

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:54:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:55:00

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:54:09
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:55:00

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:54:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:55:00

US3632127

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 '2'	System	13 Oct 2020 20:55:00

US3632127

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	13 Oct 2020 20:55:00

US3632127

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	13 Oct 2020 20:55:00

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:54:19
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:56:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:56:28
Data point term sent to Coder	System	13 Oct 2020 20:55:52
User entered 'Potassium'	(b) (4), (b) (6)	13 Oct 2020 20:55:35

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:54:20
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:55:35

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:54:23
User entered 'Hypertension'	(b) (4), (b) (6)	13 Oct 2020 20:55:35

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:54:25
User entered '10'	(b) (4), (b) (6)	13 Oct 2020 20:55:35

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:55:26
User entered 'Other (OTHER)'	(b) (4), (b) (6)	13 Oct 2020 20:55:35

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:55:28
User entered 'MeQ'	(b) (4), (b) (6)	13 Oct 2020 20:55:35

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:55:30
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Oct 2020 20:55:35

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:55:33
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:55:35

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:55:35
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 20:55:35

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:55:37
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:55:35

US3632127

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)	19 Apr 2021 17:38:35
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 23:23:55
User entered '01 Apr 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 23:23:55
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:55:40
User entered '1 Apr 2020'	(b) (4), (b) (6)	13 Oct 2020 20:55:35

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:55:42
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:55:35

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:55:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:55:35

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:55:45
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:55:35

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:55:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:55:35

US3632127

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	13 Oct 2020 20:55:35

US3632127

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	13 Oct 2020 20:55:35

US3632127

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	13 Oct 2020 20:55:35

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:56:21
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:57:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:57:18
Data point term sent to Coder	System	13 Oct 2020 20:56:54
User entered 'Magnesium'	(b) (4), (b) (6)	13 Oct 2020 20:56:12

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:56:23
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 12:38:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 12:38:13
User entered 'No (N)' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	14 Oct 2020 12:38:13
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 20:56:12
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:56:12

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:56:46
User entered 'Constipation'	(b) (4), (b) (6)	13 Oct 2020 20:56:12

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:56:49
User entered '400'	(b) (4), (b) (6)	13 Oct 2020 20:56:12

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:56:51
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 20:56:12

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:56:53
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:56:12

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:56:55
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Oct 2020 20:56:12

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:56:57
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:56:12

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:56:59
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 20:56:12

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:57:00
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:56:12

US3632127

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)	19 Apr 2021 17:38:47
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 23:24:06
User entered '01 Apr 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 23:24:06
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:57:03
User entered '1 Apr 2020'	(b) (4), (b) (6)	13 Oct 2020 20:56:12

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:57:04
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:56:12

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:57:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:56:12

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:57:09
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:56:12

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:57:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:56:12

US3632127

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	13 Oct 2020 20:56:12

US3632127

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	13 Oct 2020 20:56:12

US3632127

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	13 Oct 2020 20:56:12

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:57:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: PROBIOTICS NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:59:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:59:19
Data point term sent to Coder User entered 'Probiotic'	System (b) (4), (b) (6)	13 Oct 2020 20:57:56 13 Oct 2020 20:57:20

US3632127

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)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:38:56
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:45:02
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'Taken as a prophylaxis for general health. Updated to 'Yes'.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 18:52:19
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:17
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 18:52:17
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 18:37:03
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:57:19
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:57:20

US3632127

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 signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:57:23
User entered 'General Health'	(b) (4), (b) (6)	13 Oct 2020 20:57:20

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:57:34
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 12:44:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 12:44:35
User entered '2' reason for change: Data Entry Error	Kelly Likos (b) (4)	14 Oct 2020 12:44:35
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4) System	13 Oct 2020 20:57:20
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:57:20

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:57:37
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 12:44:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 12:44:35
User entered 'capsule (CAPSULE)' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	14 Oct 2020 12:44:35
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 20:57:20
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:57:20

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:57:40
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:57:20

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:57:43
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Oct 2020 20:57:20

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:57:45
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:57:20

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:57:47
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 20:57:20

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:57:52
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:57:20

US3632127

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)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:39:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 23:24:16
User entered '01 UNK 2015' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 23:24:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:57:53
User entered '1 UNK 2015'	(b) (4), (b) (6)	13 Oct 2020 20:57:20

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:57:57
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:57:20

US3632127

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)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:39:14
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:57:20

US3632127

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)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:39:24
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 20:57:20

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:59:16
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:57:20

US3632127

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)
User entered '1'	System	13 Oct 2020 20:57:20

US3632127

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)
User entered '1'	System	13 Oct 2020 20:57:20

US3632127

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)
User entered '804 (804)'	System	13 Oct 2020 20:57:20

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:59:32
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: MALUS SPP. VINEGAR EXTRACT, PRODUCTSYNONYM: APPLE CIDER VINEGAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 21:00:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 21:00:17
Data point term sent to Coder	System	13 Oct 2020 20:58:57
User entered 'Apple Cider Vinegar'	(b) (4), (b) (6)	13 Oct 2020 20:57:58

US3632127

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)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:39:49
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:45:35
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'Taken as a prophylaxis for general health. Updated to 'Yes'.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 18:52:39
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:34
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 18:52:34
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 18:37:12
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:59:34
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:57:58

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:59:36
User entered 'General Health'	(b) (4), (b) (6)	13 Oct 2020 20:57:58

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:59:38
User entered '480'	(b) (4), (b) (6)	13 Oct 2020 20:57:58

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:59:40
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 20:57:58

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:59:42
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:57:58

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:59:45
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Oct 2020 20:57:58

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:59:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:57:58

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:59:49
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 20:57:58

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:59:51
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:57:58

US3632127

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)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:39:55
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 23:24:24
User entered '01 UNK 2018' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 23:24:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:59:53
User entered '1 UNK 2018'	(b) (4), (b) (6)	13 Oct 2020 20:57:58

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:59:55
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:57:58

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:59:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:57:58

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:00:00
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:57:58

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:00:05
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:57:58

US3632127

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)
User entered '1'	System	13 Oct 2020 20:57:58

US3632127

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)
User entered '1'	System	13 Oct 2020 20:57:58

US3632127

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)
User entered '804 (804)'	System	13 Oct 2020 20:57:58

US3632127

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 signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:00:11
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: SAMBUCUS NIGRA, PRODUCTSYNONYM: ELDERBERRY [SAMBUCUS NIGRA] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 21:00:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 21:00:17
Data point term sent to Coder	System	13 Oct 2020 20:58:57
User entered 'Elderberry'	(b) (4), (b) (6)	13 Oct 2020 20:58:28

US3632127

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)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:40:04
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:45:52
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'Taken as a prophylaxis for general health. Updated to 'Yes'.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 18:52:45
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 18:52:43
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 18:37:20
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:00:14
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:58:28

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:00:16
User entered 'General Health'	(b) (4), (b) (6)	13 Oct 2020 20:58:28

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:00:18
User entered '1250'	(b) (4), (b) (6)	13 Oct 2020 20:58:28

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:00:20
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 20:58:28

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:00:21
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:58:28

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:00:23
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Oct 2020 20:58:28

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:00:25
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:58:28

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:00:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 20:58:28

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:00:30
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:58:28

US3632127

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)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:40:14
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 23:24:37
User entered '01 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 23:24:37
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:00:32
User entered '1 Sep 2020'	(b) (4), (b) (6)	13 Oct 2020 20:58:28

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:00:34
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:58:28

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:00:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:58:28

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:00:39
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:58:28

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:00:41
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:58:28

US3632127

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)
User entered '1'	System	13 Oct 2020 20:58:28

US3632127

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)
User entered '1'	System	13 Oct 2020 20:58:28

US3632127

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)
User entered '804 (804)'	System	13 Oct 2020 20:58:28

US3632127

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)	01 May 2021 07:44:21
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history of OSTEOARTHRITIS/RHEUMATOID ARTHRITIS worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:33:29
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history of OSTEOARTHRITIS/RHEUMATOID ARTHRITIS worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate.' answered with 'Participant reports condition not worsening and occasionally needs to take pain medication.' (Site from DM).	Sarah Wiatrek (b) (4) (b) (4)	11 Mar 2021 14:14:43
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history of OSTEOARTHRITIS/RHEUMATOID ARTHRITIS worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 13:08:31
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Feb 2021 21:44:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Feb 2021 21:44:42
Data point term sent to Coder	System	12 Feb 2021 15:19:27

US3632127

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)
Coding entries removed.	(b) (4), (b) (6)	12 Feb 2021 15:18:41
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: NAPROXEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 15:36:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 15:36:52
Data point term sent to Coder	System	15 Jan 2021 15:35:00
Coding entries removed.	(b) (4), (b) (6)	15 Jan 2021 15:34:04
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:02:52
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: NAPROXEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 15:16:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 15:16:40
Data point term sent to Coder	System	20 Oct 2020 15:15:34
User entered 'Naproxen'	Bezuayehu Mandefro (b) (4)	20 Oct 2020 15:15:17

US3632127

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)	01 May 2021 07:44:21
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:02:55
User entered 'No (N)'	Bezuayehu Mandefro (b) (4)	20 Oct 2020 15:15:17

US3632127

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)	01 May 2021 07:44:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:40:38
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User closed query 'Per DM CLR:Requery:Response noted,however kindly reconcile the indication and start date with MH eCRF so that there is an appropriate match.Thank you. ' (Site from DM).	(b) (4)	16 Feb 2021 12:08:01
Query 'Per DM CLR:Requery:Response noted,however kindly reconcile the indication and start date with MH eCRF so that there is an appropriate match.Thank you. ' answered with 'OSTEOARTHRITIS/RHEUMATOID ARTHRITIS IS ALREADY A PART OF THE PARTICIPANTS Medical history and is noted in the eCRF.' (Site from DM).	Aastha KC (b) (4)	15 Feb 2021 19:39:16
User opened query 'Per DM CLR:Requery:Response noted,however kindly reconcile the indication and start date with MH eCRF so that there is an appropriate match.Thank you. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 08:36:19
User closed query 'Per DM CLR: Please note, there is a medical condition if OSTEOARTHRITIS/RHEUMATOID ARTHRITIS (BOTH ANKLES) during this time frame as recorded . Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with MH entries so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 08:33:11
Query 'Per DM CLR: Please note, there is a medical condition if OSTEOARTHRITIS/RHEUMATOID ARTHRITIS (BOTH ANKLES) during this time frame as recorded . Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with MH entries so there is an appropriate match. ' answered with 'Reviewed and reconciled.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 15:18:56
User entered 'Osteoarthritis/Rheumatoid Arthritis' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Feb 2021 15:18:41

US3632127

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)
User opened query 'Per DM CLR: Please note, there is a medical condition if OSTEOARTHRITIS/RHEUMATOID ARTHRITIS (BOTH ANKLES) during this time frame as recorded . Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with MH entries so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 13:42:58
User closed query 'Per DM CLR: Please update the indication to reflect the type/location of the PAIN (eg, pain at injection site). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 07:10:35
Query 'Per DM CLR: Please update the indication to reflect the type/location of the PAIN (eg, pain at injection site). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 15:34:26
User entered 'Arthritis/Joint PAIN' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Jan 2021 15:34:21
DataPoint Un-verified.	(b) (4), (b) (6)	15 Jan 2021 15:34:04
User entered 'Body PAIN' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Jan 2021 15:34:04
User opened query 'Per DM CLR: Please update the indication to reflect the type/location of the PAIN (eg, pain at injection site). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 01:43:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:03:00
User entered 'Pain'	Bezuayehu Mandefro (b) (4)	20 Oct 2020 15:15:17

US3632127

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)	01 May 2021 07:44:21
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:03:03
User entered '500'	Bezuayehu Mandefro (b) (4)	20 Oct 2020 15:15:17

US3632127

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)	01 May 2021 07:44:21
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:03:04
User entered 'mg (mg)'	Bezuayehu Mandefro (b) (4)	20 Oct 2020 15:15:17

US3632127

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)	01 May 2021 07:44:21
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:03:06
User entered empty.	Bezuayehu Mandefro (b) (4)	20 Oct 2020 15:15:17

US3632127

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)	01 May 2021 07:44:21
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:03:08
User entered 'once (ONCE)'	Bezuayehu Mandefro (b) (4)	20 Oct 2020 15:15:17

US3632127

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)	01 May 2021 07:44:21
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:03:10
User entered empty.	Bezuayehu Mandefro (b) (4)	20 Oct 2020 15:15:17

US3632127

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)	01 May 2021 07:44:21
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:03:12
User entered 'Oral (ORAL)'	Bezuayehu Mandefro (b) (4)	20 Oct 2020 15:15:17

US3632127

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)	01 May 2021 07:44:21
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:03:14
User entered empty.	Bezuayehu Mandefro (b) (4)	20 Oct 2020 15:15:17

US3632127

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)	01 May 2021 07:44:21
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:03:16
User entered '13 Oct 2020'	Bezuayehu Mandefro (b) (4)	20 Oct 2020 15:15:17

US3632127

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)	01 May 2021 07:44:21
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:03:19
User entered '0'	Bezuayehu Mandefro (b) (4)	20 Oct 2020 15:15:17

US3632127

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)	01 May 2021 07:44:21
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:03:23
User entered 'No (N)'	Bezuayehu Mandefro (b) (4)	20 Oct 2020 15:15:17

US3632127

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)	01 May 2021 07:44:21
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:03:27
User entered '13 Oct 2020'	Bezuayehu Mandefro (b) (4)	20 Oct 2020 15:15:17

US3632127

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)	01 May 2021 07:44:21
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:03:32
User entered 'No (N)'	Bezuayehu Mandefro (b) (4)	20 Oct 2020 15:15:17

US3632127

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)	01 May 2021 07:44:21
User entered empty.	System	20 Oct 2020 15:15:17

US3632127

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)	01 May 2021 07:44:21
User entered empty.	System	20 Oct 2020 15:15:17

US3632127

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)	01 May 2021 07:44:21
User entered empty.	System	20 Oct 2020 15:15:17

US3632127

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.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:01:26
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: PRAVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 15:05:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 15:05:22
Data point term sent to Coder	System	03 Nov 2020 13:24:29
User entered 'Pravastatin'	(b) (4), (b) (6)	03 Nov 2020 13:24:03

US3632127

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.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:01:29
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 13:24:03

US3632127

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.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
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)	18 Jan 2021 07:08:25
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 in MH' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 15:36:21
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)	14 Jan 2021 01:43:56
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:01:42
User entered 'Slightly Elevated Cholesterol'	(b) (4), (b) (6)	03 Nov 2020 13:24:03

US3632127

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.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:01:44
User entered '10'	(b) (4), (b) (6)	03 Nov 2020 13:24:03

US3632127

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.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:01:46
User entered 'mg (mg)'	(b) (4), (b) (6)	03 Nov 2020 13:24:03

US3632127

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.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:02:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 13:24:03

US3632127

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.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:02:06
User entered 'once daily (QD)'	(b) (4), (b) (6)	03 Nov 2020 13:24:03

US3632127

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.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:02:07
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 13:24:03

US3632127

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.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:02:09
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Nov 2020 13:24:03

US3632127

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.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:02:12
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 13:24:03

US3632127

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.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:02:15
User entered '19 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 13:24:03

US3632127

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.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:02:17
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 13:24:03

US3632127

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.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:02:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 13:24:03

US3632127

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.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:02:30
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 13:24:03

US3632127

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.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:02:33
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 13:24:03

US3632127

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	03 Nov 2020 13:24:03

US3632127

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	03 Nov 2020 13:24:03

US3632127

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	03 Nov 2020 13:24:03

US3632127

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)	03 May 2021 06:13:47
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:04:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 16:13:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 16:13:21
Data point term sent to Coder	System	03 Nov 2020 16:12:04
User entered 'Vitamin D3'	(b) (4), (b) (6)	03 Nov 2020 16:12:01

US3632127

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)	03 May 2021 06:13:47
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:41:47
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Jan 2021 07:08:36
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 15:36:37
DataPoint Un-verified.	(b) (4), (b) (6)	15 Jan 2021 15:36:30
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Jan 2021 15:36:30
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 01:44:53
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:04:27
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 16:12:01

US3632127

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)	03 May 2021 06:13:47
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:04:30
User entered 'To help with bone health'	(b) (4), (b) (6)	03 Nov 2020 16:12:01

US3632127

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)	03 May 2021 06:13:47
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:04:33
User entered '5000'	(b) (4), (b) (6)	03 Nov 2020 16:12:01

US3632127

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)	03 May 2021 06:13:47
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:04:35
User entered 'IU (IU)'	(b) (4), (b) (6)	03 Nov 2020 16:12:01

US3632127

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)	03 May 2021 06:13:47
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:04:37
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 16:12:01

US3632127

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)	03 May 2021 06:13:47
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4)	17 Nov 2020 18:05:19
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 18:04:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:04:39
User entered 'every week (QS)'	(b) (4), (b) (6)	03 Nov 2020 16:12:01

US3632127

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)	03 May 2021 06:13:47
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:05:21
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 16:12:01

US3632127

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)	03 May 2021 06:13:47
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:05:23
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Nov 2020 16:12:01

US3632127

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)	03 May 2021 06:13:47
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:05:25
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 16:12:01

US3632127

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)	03 May 2021 06:13:47
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:05:28
User entered '01 May 2020'	(b) (4), (b) (6)	03 Nov 2020 16:12:01

US3632127

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)	03 May 2021 06:13:47
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:05:31
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 16:12:01

US3632127

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)	03 May 2021 06:13:47
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:41:56
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:54:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Feb 2021 17:54:51
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:05:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 16:12:01

US3632127

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)	03 May 2021 06:13:47
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:41:57
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:54:51
User entered 'un UNK 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Feb 2021 17:54:51
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:05:35
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 16:12:01

US3632127

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)	03 May 2021 06:13:47
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:05:37
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 16:12:01

US3632127

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)	03 May 2021 06:13:47
User entered '1'	System	03 Nov 2020 16:12:01

US3632127

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)	03 May 2021 06:13:47
User entered '1'	System	03 Nov 2020 16:12:01

US3632127

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)	03 May 2021 06:13:47
User entered '803 (803)'	System	03 Nov 2020 16:12:01

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:05:47
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC SODIUM, PRODUCTSYNONYM: VOLTAREN [DICLOFENAC SODIUM] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Nov 2020 05:54:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Nov 2020 05:54:38
Data point term sent to Coder	System	03 Nov 2020 19:24:51
User entered 'VOLTAREN GEL (Diclofenac Sodium 1% Gel)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 19:24:33
Data point term sent to Coder	System	03 Nov 2020 16:13:05
User entered 'Voltaren Gel'	(b) (4), (b) (6)	03 Nov 2020 16:12:42

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:05:50
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 16:12:42

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:05:56
User entered 'Rheumatoid Arthritis'	(b) (4), (b) (6)	03 Nov 2020 16:12:42

US3632127

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)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:42:21
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User closed query 'Per DM CLR: Please review the dose/unit to consider if no. of application would be a more appropriate response (e.g. Dose = 2, Unit = Other: Applications). Update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 07:08:48
Query 'Per DM CLR: Please review the dose/unit to consider if no. of application would be a more appropriate response (e.g. Dose = 2, Unit = Other: Applications). Update as appropriate, otherwise clarify. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 15:37:41
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Jan 2021 15:37:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Jan 2021 15:37:36
User entered '2' reason for change: New Information	(b) (4), (b) (6)	15 Jan 2021 15:37:36
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Jan 2021 15:37:20
DataPoint Un-verified.	(b) (4), (b) (6)	15 Jan 2021 15:37:20
User entered empty; reason for change New Information	(b) (4), (b) (6)	15 Jan 2021 15:37:20
User opened query 'Per DM CLR: Please review the dose/unit to consider if no. of application would be a more appropriate response (e.g. Dose = 2, Unit = Other: Applications). Update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 01:45:26
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:05:59
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 19:24:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 19:24:33

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EAB) (1725)

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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)
User entered '2' reason for change: New Information	(b) (4), (b) (6)	03 Nov 2020 19:24:33
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 16:12:42
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 16:12:42

US3632127

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)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:42:29
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:37:20
User entered 'Other (OTHER)' reason for change: New Information	(b) (4), (b) (6)	15 Jan 2021 15:37:20
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:06:00
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 19:24:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 19:24:33
User entered 'g (g)' reason for change: New Information	(b) (4), (b) (6)	03 Nov 2020 19:24:33
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 16:12:42
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 16:12:42

US3632127

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)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:42:31
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:37:20
User entered 'Application' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Jan 2021 15:37:20
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:06:03
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 16:12:42

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:06:05
User entered 'as needed (PRN)'	(b) (4), (b) (6)	03 Nov 2020 16:12:42

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:06:08
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 16:12:42

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:06:10
User entered 'Topical (TOPICAL)'	(b) (4), (b) (6)	03 Nov 2020 16:12:42

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:06:11
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 16:12:42

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:06:14
User entered '01 UNK 2019'	(b) (4), (b) (6)	03 Nov 2020 16:12:42

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:06:16
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 16:12:42

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:06:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 16:12:42

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:06:20
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 16:12:42

US3632127

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)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:06:22
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 16:12:42

US3632127

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)
User entered empty.	System	03 Nov 2020 16:12:42

US3632127

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)
User entered empty.	System	03 Nov 2020 16:12:42

US3632127

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)
User entered empty.	System	03 Nov 2020 16:12:42

US3632127

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)	01 May 2021 07:44:25
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	05 Apr 2021 01:17:38
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 10:10:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 10:10:35
Data point term sent to Coder Coding entries removed.	System Christina Bacher (b) (4) (b) (4)	20 Nov 2020 14:57:27 20 Nov 2020 14:56:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:06:31
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 02:29:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 02:29:43
Data point term sent to Coder User entered 'Ceftriaxone'	System (b) (4), (b) (6)	10 Nov 2020 21:34:07 10 Nov 2020 21:33:27

US3632127

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)	01 May 2021 07:44:25
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:06:33
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 21:33:27

US3632127

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)	01 May 2021 07:44:25
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:07:55
User closed query 'Per source, indication is for the AE of Sexual Assault. Please verify with source and update indication in EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 17:07:45
Query 'Per source, indication is for the AE of Sexual Assault. Please verify with source and update indication in EDC accordingly.' answered with 'UPDATED' (Site from CRA).	Christina Bacher (b) (4)	20 Nov 2020 14:56:53
User entered 'Sexual assault (AE)- presumptive treatment of STI's' reason for change: New Information	Christina Bacher (b) (4)	20 Nov 2020 14:56:47
User opened query 'Per source, indication is for the AE of Sexual Assault. Please verify with source and update indication in EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 18:08:11
User entered 'presumptive treatment for STI'	(b) (4), (b) (6)	10 Nov 2020 21:33:27

US3632127

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)	01 May 2021 07:44:25
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:08:15
User entered '250'	(b) (4), (b) (6)	10 Nov 2020 21:33:27

US3632127

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)	01 May 2021 07:44:25
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:08:17
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Nov 2020 21:33:27

US3632127

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)	01 May 2021 07:44:25
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:08:19
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 21:33:27

US3632127

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)	01 May 2021 07:44:25
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:08:22
User entered 'once (ONCE)'	(b) (4), (b) (6)	10 Nov 2020 21:33:27

US3632127

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)	01 May 2021 07:44:25
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:08:25
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 21:33:27

US3632127

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)	01 May 2021 07:44:25
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:08:27
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	10 Nov 2020 21:33:27

US3632127

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)	01 May 2021 07:44:25
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:08:29
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 21:33:27

US3632127

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)	01 May 2021 07:44:25
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:08:32
User entered '07 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 21:33:27

US3632127

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)	01 May 2021 07:44:25
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:08:35
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 21:33:27

US3632127

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)	01 May 2021 07:44:25
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:08:38
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 21:33:27

US3632127

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)	01 May 2021 07:44:25
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:08:39
User entered '07 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 21:33:27

US3632127

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)	01 May 2021 07:44:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:42:47
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 07:09:25
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 15:38:30
DataPoint Un-verified.	(b) (4), (b) (6)	15 Jan 2021 15:37:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Jan 2021 15:37:58

US3632127

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)
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 01:46:04
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:08:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 21:33:27

US3632127

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)	01 May 2021 07:44:25
User entered empty.	System	10 Nov 2020 21:33:27

US3632127

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)	01 May 2021 07:44:25
User entered empty.	System	10 Nov 2020 21:33:27

US3632127

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)	01 May 2021 07:44:25
User entered empty.	System	10 Nov 2020 21:33:27

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:08:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:28
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: ZITHROMAX - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Nov 2020 05:24:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Nov 2020 05:24:43
Data point term sent to Coder	System	20 Nov 2020 14:57:28
Coding entries removed.	Christina Bacher (b) (4)	20 Nov 2020 14:57:21
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:09:38
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: ZITHROMAX - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Nov 2020 04:41:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Nov 2020 04:41:49
Data point term sent to Coder	System	10 Nov 2020 21:37:10
User entered 'Zithromax'	(b) (4), (b) (6)	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:28
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:28
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:08:46
User closed query 'Per source, indication is for the AE of Sexual Assault. Please verify with source and update indication in EDC accordingly. ' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 17:08:42
Query 'Per source, indication is for the AE of Sexual Assault. Please verify with source and update indication in EDC accordingly. ' answered with 'updated' (Site from CRA).	Christina Bacher (b) (4)	20 Nov 2020 14:57:29
User entered 'SEXUAL ASSAULT (AE)- PRESUMPTIVE TREATMENT OF STI'S' reason for change: New Information	Christina Bacher (b) (4)	20 Nov 2020 14:57:21
User opened query 'Per source, indication is for the AE of Sexual Assault. Please verify with source and update indication in EDC accordingly. ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 18:10:18
User entered 'presumptive treatment for STI'	(b) (4), (b) (6)	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:28
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:10:22
User entered '1'	(b) (4), (b) (6)	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:28
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:10:23
User entered 'g (g)'	(b) (4), (b) (6)	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

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)	01 May 2021 07:44:28
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:10:25
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:28
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:10:28
User entered 'once (ONCE)'	(b) (4), (b) (6)	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:08:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:28
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:10:29
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:28
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:10:31
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

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)	01 May 2021 07:44:28
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:10:32
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:08:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:28
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:10:34
User entered '07 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:28
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:10:36
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:28
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:10:43
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

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)	01 May 2021 07:44:28
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:10:48
User entered '07 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

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)	01 May 2021 07:44:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:43:58
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification. '(Site from DM).	(b) (4), (b) (6)	18 Jan 2021 07:09:32
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 15:38:22
DataPoint Un-verified.	(b) (4), (b) (6)	15 Jan 2021 15:38:14
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Jan 2021 15:38:14

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:08:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 01:46:33
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:10:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:28
User entered empty.	System	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:28
User entered empty.	System	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:28
User entered empty.	System	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:08:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:30
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	05 Apr 2021 01:17:38
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE, PRODUCTSYNONYM: FLAGYL [METRONIDAZOLE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 12:29:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 12:29:54
Data point term sent to Coder Coding entries removed.	System Christina Bacher (b) (4) (b) (4)	20 Nov 2020 14:58:29 20 Nov 2020 14:57:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:11:02
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE, PRODUCTSYNONYM: FLAGYL [METRONIDAZOLE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 23:50:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 23:50:44
Data point term sent to Coder User entered 'Flagyl'	System (b) (4), (b) (6)	10 Nov 2020 21:38:13 10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:30
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:11:04
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:30
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:09:17
User closed query 'Per source, indication is for the AE of Sexual Assault. Please verify with source and update indication in EDC accordingly. ' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 17:09:14
Query 'Per source, indication is for the AE of Sexual Assault. Please verify with source and update indication in EDC accordingly. ' answered with 'UPDATED' (Site from CRA).	Christina Bacher (b) (4)	20 Nov 2020 14:57:55
User entered 'SEXUAL ASSAULT (AE)- PRESUMPTIVE TREATMENT OF STI'S' reason for change: New Information	Christina Bacher (b) (4)	20 Nov 2020 14:57:48
User opened query 'Per source, indication is for the AE of Sexual Assault. Please verify with source and update indication in EDC accordingly. ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 18:11:19
User entered 'presumptive treatment for STI'	(b) (4), (b) (6)	10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:30
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:11:27
User entered '2'	(b) (4), (b) (6)	10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:30
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:11:28
User entered 'g (g)'	(b) (4), (b) (6)	10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

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)	01 May 2021 07:44:30
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:11:32
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:30
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:11:34
User entered 'once (ONCE)'	(b) (4), (b) (6)	10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:08:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:30
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:11:36
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:30
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:11:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

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)	01 May 2021 07:44:30
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:11:40
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:08:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:30
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:11:42
User entered '07 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:30
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:11:44
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:30
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:11:50
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

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)	01 May 2021 07:44:30
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:11:55
User entered '07 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

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)	01 May 2021 07:44:30
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:44:15
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 07:09:43
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 15:38:46
DataPoint Un-verified.	(b) (4), (b) (6)	15 Jan 2021 15:38:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Jan 2021 15:38:40

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:08:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 01:47:05
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:11:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:30
User entered empty.	System	10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:30
User entered empty.	System	10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:30
User entered empty.	System	10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:08:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:36
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:12:08
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: OTHER ANTIVIRALS, PRODUCT: DOLUTEGRAVIR SODIUM, PRODUCTSYNONYM: TIVICAY - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:11:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:11:41
Data point term sent to Coder	System	13 Nov 2020 19:53:44
User entered 'Tivicay (dolutegravir)'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:52:57

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:36
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:14:25
User entered 'Yes (Y)'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:52:57

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:36
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:14:28
User entered 'Sexual Assault (AE #1)'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:52:57

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:36
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:14:31
User entered '50'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:52:57

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:36
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:14:33
User entered 'mg (mg)'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:52:57

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

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)	01 May 2021 07:44:36
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:14:38
User entered empty.	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:52:57

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:36
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:14:40
User entered 'once daily (QD)'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:52:57

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:08:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:36
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:14:41
User entered empty.	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:52:57

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:36
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:14:44
User entered 'Oral (ORAL)'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:52:57

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

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)	01 May 2021 07:44:36
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:14:46
User entered empty.	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:52:57

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:08:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:36
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:14:48
User entered '12 Nov 2020'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:52:57

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:36
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:15:56
User entered '0'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:52:57

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:36
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:44:25
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:24:05
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	11 Dec 2020 17:24:05
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:15:58
User entered 'Yes (Y)'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:52:57

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

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)	01 May 2021 07:44:36
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:44:44
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:24:05
User entered '20 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	11 Dec 2020 17:24:05
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:15:59
User entered empty.	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:52:57

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

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)	01 May 2021 07:44:36
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:16:01
User entered 'No (N)' reason for change: Data Entry Error	Aastha KC (b) (4)	13 Nov 2020 19:53:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	13 Nov 2020 19:53:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 19:53:04
User entered 'Yes (Y)' reason for change: Data Entry Error	System	13 Nov 2020 19:53:04
User opened query 'Data is required. Please complete.' (Site from System).	Aastha KC (b) (4)	13 Nov 2020 19:53:04
User entered empty.	(b) (4)	13 Nov 2020 19:52:57
	Aastha KC (b) (4)	13 Nov 2020 19:52:57
	(b) (4)	

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:36
User entered '1'	System	13 Nov 2020 19:52:57

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:36
User entered '1'	System	13 Nov 2020 19:52:57

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:36
User entered '804 (804)'	System	13 Nov 2020 19:52:57

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:08:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:38
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:17:06
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS, PRODUCT: EMTRICITABINE;TENOFOVIR DISOPROXIL FUMARATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:50:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:50:45
Data point term sent to Coder	System	13 Nov 2020 19:55:48
User entered 'emtricitabine and tenofovir disoproxil fumarate'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:55:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:38
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:17:08
User entered 'Yes (Y)'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:55:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:38
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:17:10
User entered 'Sexual Assault'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:55:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:38
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:17:12
User entered '200/300'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:55:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:38
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:17:14
User entered 'mg (mg)'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:55:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

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)	01 May 2021 07:44:38
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:17:16
User entered empty.	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:55:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:38
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:17:17
User entered 'once daily (QD)'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:55:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:08:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:38
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:17:18
User entered empty.	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:55:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:38
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:17:21
User entered 'Oral (ORAL)'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:55:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

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)	01 May 2021 07:44:38
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:17:23
User entered empty.	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:55:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:08:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:38
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:17:25
User entered '12 Nov 2020'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:55:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:38
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:17:26
User entered '0'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:55:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:44:55
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'No (N)' reason for change: New Information	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 17:23:38
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 18:17:30
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:17:28
User entered 'Yes (Y)'	Aastha KC (b) (4)	13 Nov 2020 19:55:12
	(b) (4)	

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

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)	01 May 2021 07:44:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:44:58
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered '20 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 17:23:38
User entered empty.	Aastha KC (b) (4)	13 Nov 2020 19:55:12
	(b) (4)	

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

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)	01 May 2021 07:44:38
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
DataPoint Verified.	(b) (4)	17 Nov 2020 18:23:29
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 18:21:34
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:21:28
User entered 'No (N)'	Aastha KC (b) (4)	13 Nov 2020 19:55:12
	(b) (4)	

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:38
User entered '1'	System	13 Nov 2020 19:55:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:38
User entered '1'	System	13 Nov 2020 19:55:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:38
User entered '804 (804)'	System	13 Nov 2020 19:55:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:08:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:46:56
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
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: NAPROXEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:06:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:06:04
Data point term sent to Coder	System	20 Nov 2020 14:55:25
User entered 'Naproxen'	Christina Bacher (b) (4) (b) (4)	20 Nov 2020 14:55:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:46:56
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	05 Apr 2021 01:17:38
User entered 'No (N)'	Christina Bacher (b) (4) (b) (4)	20 Nov 2020 14:55:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:46:56
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Fractured toe (AE)'	(b) (4) Christina Bacher (b) (4)	20 Nov 2020 14:55:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:46:56
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered '500'	(b) (4) Christina Bacher (b) (4)	20 Nov 2020 14:55:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:46:56
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'mg (mg)'	(b) (4) Christina Bacher (b) (4)	20 Nov 2020 14:55:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

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)	01 May 2021 07:44:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:46:56
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	05 Apr 2021 01:17:38
User entered empty.	Christina Bacher (b) (4) (b) (4)	20 Nov 2020 14:55:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:46:56
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	05 Apr 2021 01:17:38
User entered 'once daily (QD)'	Christina Bacher (b) (4) (b) (4)	20 Nov 2020 14:55:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:08:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:46:56
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	05 Apr 2021 01:17:38
User entered empty.	Christina Bacher (b) (4) (b) (4)	20 Nov 2020 14:55:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:46:56
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Oral (ORAL)'	(b) (4) Christina Bacher (b) (4)	20 Nov 2020 14:55:02
	(b) (4)	

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

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)	01 May 2021 07:44:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:46:56
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered empty.	(b) (4) Christina Bacher (b) (4)	20 Nov 2020 14:55:02
	(b) (4)	

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:08:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:46:56
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered '7 Nov 2020'	(b) (4) Christina Bacher (b) (4)	20 Nov 2020 14:55:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:46:56
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered '0'	(b) (4) Christina Bacher (b) (4)	20 Nov 2020 14:55:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:46:56
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'Reviewed and reconciled.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 08:29:40
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'Reviewed and reconciled.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 15:21:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Feb 2021 15:20:18
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 01:16:04
User entered 'Yes (Y)'	Christina Bacher (b) (4)	20 Nov 2020 14:55:02
	(b) (4)	

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

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)	01 May 2021 07:44:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:46:56
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered '15 Dec 2020' reason for change: Data Entry Error	(b) (4)	
User entered empty.	(b) (4), (b) (6)	12 Feb 2021 15:20:18
	Christina Bacher (b) (4)	20 Nov 2020 14:55:02
	(b) (4)	

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

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)	01 May 2021 07:44:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:46:56
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	05 Apr 2021 01:17:38
User entered 'No (N)'	Christina Bacher (b) (4) (b) (4)	20 Nov 2020 14:55:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:40
User entered '1'	System	20 Nov 2020 14:55:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:40
User entered '1'	System	20 Nov 2020 14:55:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:40
User entered '804 (804)'	System	20 Nov 2020 14:55:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:08:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:47:00
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	22 Jan 2021 20:47:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Jan 2021 20:47:05
Data point term sent to Coder	System	22 Jan 2021 20:46:42
User entered 'Tylenol'	(b) (4), (b) (6)	22 Jan 2021 20:46:08

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:47:00
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	05 Apr 2021 01:17:38
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Jan 2021 20:46:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Jan 2021 20:46:30
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 20:46:30
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Jan 2021 20:46:08
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 20:46:08

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:47:00
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
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)	12 Mar 2021 16:36:54
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 'This medication is related to an AR. From our understanding of the protocol, we were not supposed to list ARs as AEs for the OL visits. Please confirm if you would like this listed as an AE or if this medication should be removed.' (Site from DM).	Sarah Wiatrek (b) (4) (b) (4)	11 Mar 2021 14:46:21
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)	25 Feb 2021 23:56:16
User entered 'Arm soreness after OL vaccination'	(b) (4), (b) (6)	22 Jan 2021 20:46:08

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:47:00
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered '1,000'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:46:08

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:47:00
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:46:08

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

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)	01 May 2021 07:44:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:47:00
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:46:08

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:47:00
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:46:08

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:08:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:47:00
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:46:08

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:47:00
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:46:08

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

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)	01 May 2021 07:44:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:47:00
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:46:08

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:08:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:47:00
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:46:08

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:47:00
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:46:08

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:47:00
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:46:08

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

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)	01 May 2021 07:44:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:47:00
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:46:08

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

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)	01 May 2021 07:44:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:47:00
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:46:08

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:48
User entered '1'	System	22 Jan 2021 20:46:08

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:48
User entered '1'	System	22 Jan 2021 20:46:08

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:48
User entered '804 (804)'	System	22 Jan 2021 20:46:08

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:08:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:47:06
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
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: NAPROXEN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Jan 2021 23:47:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 23:47:08
Data point term sent to Coder	System	22 Jan 2021 20:48:43
User entered 'Naproxen'	(b) (4), (b) (6)	22 Jan 2021 20:48:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:47:06
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:48:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:47:06
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
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)	12 Mar 2021 16:37:08
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 'This medication is related to an AR. From our understanding of the protocol, we were not supposed to list ARs as AEs for the OL visits. Please confirm if you would like this listed as an AE or if this medication should be removed.' (Site from DM).	Sarah Wiatrek (b) (4) (b) (4)	11 Mar 2021 14:45:50
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)	25 Feb 2021 23:56:35
User entered 'pain in arm after OL vaccination'	(b) (4), (b) (6)	22 Jan 2021 20:48:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:47:06
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered '550'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:48:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:47:06
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:48:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

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)	01 May 2021 07:44:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:47:06
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:48:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:47:06
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:48:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:08:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:47:06
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:48:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:47:06
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:48:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

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)	01 May 2021 07:44:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:47:06
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:48:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:08:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:47:06
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:48:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:47:06
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:48:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:47:06
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:48:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

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)	01 May 2021 07:44:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:47:06
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:48:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

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)	01 May 2021 07:44:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:47:06
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:48:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:50
User entered empty.	System	22 Jan 2021 20:48:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:50
User entered empty.	System	22 Jan 2021 20:48:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:50
User entered empty.	System	22 Jan 2021 20:48:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:08:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:02:38
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROCODONE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	22 Jan 2021 23:25:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 23:25:08
Data point term sent to Coder	System	22 Jan 2021 20:51:45
User entered 'Hydrocodone'	(b) (4), (b) (6)	22 Jan 2021 20:51:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:02:41
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:51:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:02:48
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
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)	12 Mar 2021 16:35:12
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 'This medication is related to an AR. From our understanding of the protocol, we were not supposed to list ARs as AEs for the OL visits. Please confirm if you would like this listed as an AE or if this medication should be removed.' (Site from DM).	Sarah Wiatrek (b) (4) (b) (4)	11 Mar 2021 14:44:44
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)	25 Feb 2021 23:56:47
User entered 'left arm pain after OL vaccine'	(b) (4), (b) (6)	22 Jan 2021 20:51:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:02:58
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:34:41
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' answered with 'This medication is not a combination drug (ie. Vicodin). ' (Site from DM).	Sarah Wiatrek (b) (4) (b) (4)	11 Mar 2021 14:45:11
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 23:56:55
User entered '7.5'	(b) (4), (b) (6)	22 Jan 2021 20:51:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:03:17
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:51:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

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)	01 May 2021 07:44:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:03:19
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:51:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:03:21
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:51:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:08:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:03:24
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:51:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:03:43
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:51:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

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)	01 May 2021 07:44:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:03:48
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:51:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:08:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:03:53
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered '17 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:51:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:03:55
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:51:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:03:58
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:51:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

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)	01 May 2021 07:44:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:04:00
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered '17 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:51:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

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)	01 May 2021 07:44:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:42:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:26:36
User closed query 'This is noted as an AR; please review and update response.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 15:26:34
Query 'This is noted as an AR; please review and update response.' answered with 'Updated' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 18:52:57
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 18:52:36
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 18:52:36
User opened query 'This is noted as an AR; please review and update response.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 18:05:05
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:51:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:52
User entered empty.	System	22 Jan 2021 20:51:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:52
User entered empty.	System	22 Jan 2021 20:51:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:52
User entered empty.	System	22 Jan 2021 20:51:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:08:05

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Feb 2021 17:57:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Feb 2021 17:57:48
Data point term sent to Coder	System	12 Feb 2021 17:57:02
User entered 'Vitamin D3'	(b) (4), (b) (6)	12 Feb 2021 17:56:11

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User closed query 'Per CDM: As per CCGs, Prophylaxis applies to any medications used for prevention (i.e. vitamins, supplements, ASA (cardiac), bone maintenance, etc.). So please verify if field 'Prophylaxis' should be updated to 'Yes', else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 10:10:27
Query 'Per CDM: As per CCGs, Prophylaxis applies to any medications used for prevention (i.e. vitamins, supplements, ASA (cardiac), bone maintenance, etc.). So please verify if field 'Prophylaxis' should be updated to 'Yes', else clarify.' answered with 'Taken as a prophylaxis for bones ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 19:45:35
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4), (b) (6)	18 Feb 2021 19:45:19
User opened query 'Per CDM: As per CCGs, Prophylaxis applies to any medications used for prevention (i.e. vitamins, supplements, ASA (cardiac), bone maintenance, etc.). So please verify if field 'Prophylaxis' should be updated to 'Yes', else clarify.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 06:26:17
User entered 'No (N)'	(b) (4), (b) (6)	12 Feb 2021 17:56:11

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'general bone health'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:56:11

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User closed query 'Per DM CLR: Please review and remove the units from the dose field and add unit of measurement for this medication to the unit field. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:37:35
Query 'Per DM CLR: Please review and remove the units from the dose field and add unit of measurement for this medication to the unit field. Update Con Med eCRF as appropriate.' answered with 'Update. ' (Site from DM).	Sarah Wiatrek (b) (4) (b) (4)	11 Mar 2021 14:49:06
User entered '25' reason for change: Per Query Resolution	Sarah Wiatrek (b) (4) (b) (4)	11 Mar 2021 14:49:00
User opened query 'Per DM CLR: Please review and remove the units from the dose field and add unit of measurement for this medication to the unit field. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 13:08:46
User entered '25 mcg'	(b) (4), (b) (6)	12 Feb 2021 17:56:11

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'ug (ug)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:56:11

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:08:05

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:56:11

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:56:11

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:08:05

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:56:11

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:56:11

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

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)	19 Apr 2021 18:07:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:56:11

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:08:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'un UNK 2021'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:56:11

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:08:05

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:56:11

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:56:11

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

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)	19 Apr 2021 18:07:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:56:11

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

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)	19 Apr 2021 18:07:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:56:11

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Feb 2021 17:56:11

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Feb 2021 17:56:11

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Feb 2021 17:56:11

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:08:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:09
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: TRIAZOLE DERIVATIVES, PRODUCT: FLUCONAZOLE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Feb 2021 14:24:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Feb 2021 14:24:53
Data point term sent to Coder	System	25 Feb 2021 14:24:15
User entered 'Fluconazole'	(b) (4), (b) (6)	25 Feb 2021 14:24:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:09
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:24:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:09
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Urinary Tract Infection'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:24:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:09
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered '150'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:24:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:09
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:24:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

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)	01 May 2021 07:45:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:09
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:24:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:09
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:24:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:08:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:09
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'once daily for 2 days'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:24:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:09
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:24:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

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)	01 May 2021 07:45:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:09
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:24:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:08:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:09
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:24:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:09
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:24:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:09
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	05 Apr 2021 01:17:38
User entered 'No (N)' reason for change: Data Entry Error	Sarah Wiatrek (b) (4) (b) (4)	30 Mar 2021 18:11:04
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 14:24:23
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 14:24:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

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)	01 May 2021 07:45:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:09
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	05 Apr 2021 01:17:38
User entered '26 Feb 2021' reason for change: New Information	Sarah Wiatrek (b) (4) (b) (4)	30 Mar 2021 18:11:04
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	25 Feb 2021 14:24:31
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	25 Feb 2021 14:24:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 14:24:31
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	25 Feb 2021 14:24:23
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	25 Feb 2021 14:24:12
User entered '26 Feb 2021'	(b) (4), (b) (6)	25 Feb 2021 14:24:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

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)	01 May 2021 07:45:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:09
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:24:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:01
User entered empty.	System	25 Feb 2021 14:24:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:01
User entered empty.	System	25 Feb 2021 14:24:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:01
User entered empty.	System	25 Feb 2021 14:24:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:08:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:35
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: NITROFURAN DERIVATIVES, PRODUCT: NITROFURANTOIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Feb 2021 14:41:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Feb 2021 14:41:53
Data point term sent to Coder	System	25 Feb 2021 14:26:16
User entered 'Nitrofurantoin'	(b) (4), (b) (6)	25 Feb 2021 14:26:16

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:35
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:26:16

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:35
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Urinary Tract Infection'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:26:16

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:35
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered '100'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:26:16

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:35
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:26:16

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

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)	01 May 2021 07:45:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:35
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:26:16

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:35
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	(b) (4) System	30 Mar 2021 18:12:24
User entered 'other (OTHER)' reason for change: Data Entry Error	Sarah Wiatrek (b) (4)	30 Mar 2021 18:12:24
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	(b) (4) System	30 Mar 2021 18:11:42
User entered 'twice daily (BID)' reason for change: Data Entry Error	Kelly Likos (b) (4)	19 Mar 2021 17:57:44
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:26:16

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:08:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:35
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	05 Apr 2021 01:17:38
User entered 'twice daily for 5 DAYS' reason for change: Data Entry Error	Sarah Wiatrek (b) (4) (b) (4)	30 Mar 2021 18:12:24
User entered '5 days' reason for change: Data Entry Error	Sarah Wiatrek (b) (4) (b) (4)	30 Mar 2021 18:11:42
User closed query 'Per CDM Query: Please confirm if the available option for Frequency of Twice Daily would be a better choice. If so, please update CRF accordingly. Thank you' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 16:02:47
Query 'Per CDM Query: Please confirm if the available option for Frequency of Twice Daily would be a better choice. If so, please update CRF accordingly. Thank you' answered with 'updated' (Site from DM).	Kelly Likos (b) (4) (b) (4)	19 Mar 2021 17:57:51
User entered empty; reason for change Data Entry Error	Kelly Likos (b) (4) (b) (4)	19 Mar 2021 17:57:44
User opened query 'Per CDM Query: Please confirm if the available option for Frequency of Twice Daily would be a better choice. If so, please update CRF accordingly. Thank you' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 17:44:56
User entered 'twice daily for 5 days'	(b) (4), (b) (6)	25 Feb 2021 14:26:16

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:35
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:26:16

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

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)	01 May 2021 07:45:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:35
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:26:16

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:08:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:35
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:26:16

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:35
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:26:16

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:35
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'No (N)' reason for change: New Information	(b) (4) Sarah Wiatrek (b) (4)	11 Mar 2021 14:18:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Feb 2021 14:26:16

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

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)	01 May 2021 07:45:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:35
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	05 Apr 2021 01:17:38
User entered '01 Mar 2021' reason for change: New Information	Sarah Wiatrek (b) (4) (b) (4)	11 Mar 2021 14:18:41
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 14:26:16

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

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)	01 May 2021 07:45:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:35
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:26:16

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:03
User entered empty.	System	30 Mar 2021 18:12:24
User entered '2'	System	19 Mar 2021 17:57:44
User entered empty.	System	25 Feb 2021 14:26:16

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:03
User entered empty.	System	30 Mar 2021 18:12:24
User entered '1'	System	19 Mar 2021 17:57:44
User entered empty.	System	25 Feb 2021 14:26:16

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:03
User entered empty.	System	30 Mar 2021 18:12:24
User entered '804 (804)'	System	19 Mar 2021 17:57:44
User entered empty.	System	25 Feb 2021 14:26:16

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:08:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: CENTRALLY ACTING ANTI OBESITY PRODUCTS, PRODUCT: PHENTERMINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 17:25:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 17:25:39
Data point term sent to Coder	System	07 Apr 2021 17:24:06
Coding entries removed.	Aastha KC (b) (4) (b) (4)	07 Apr 2021 17:23:51
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	05 Apr 2021 01:17:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: CENTRALLY ACTING ANTI OBESITY PRODUCTS, PRODUCT: PHENTERMINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Mar 2021 14:49:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Mar 2021 14:49:49
Data point term sent to Coder	System	11 Mar 2021 14:48:53
User entered 'Phentermine'	Sarah Wiatrek (b) (4) (b) (4)	11 Mar 2021 14:48:24

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:39
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'No (N)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	11 Mar 2021 14:48:24

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:39
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:37:15
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, rather than the drug class or action of the medication. 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)	08 Apr 2021 09:44:50
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'SEVERE OBESITY added' (Site from DM).	Aastha KC (b) (4) (b) (4)	07 Apr 2021 17:24:10
Signature has been broken.	Aastha KC (b) (4) (b) (4)	07 Apr 2021 17:23:51
User entered 'Severe Obesity' reason for change: Data Entry Error	Aastha KC (b) (4) (b) (4)	07 Apr 2021 17:23:51
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, rather than the drug class or action of the medication. 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)	07 Apr 2021 11:45:26
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	05 Apr 2021 01:17:38
User entered 'Appetite suppressant'	Sarah Wiatrek (b) (4) (b) (4)	11 Mar 2021 14:48:24

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:39
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered '37.5'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	11 Mar 2021 14:48:24

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:39
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'mg (mg)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	11 Mar 2021 14:48:24

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

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)	01 May 2021 07:45:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:39
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	05 Apr 2021 01:17:38
User entered empty.	Sarah Wiatrek (b) (4) (b) (4)	11 Mar 2021 14:48:24

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:39
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'once daily (QD)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	11 Mar 2021 14:48:24

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:08:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:39
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	05 Apr 2021 01:17:38
User entered empty.	Sarah Wiatrek (b) (4) (b) (4)	11 Mar 2021 14:48:24

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:39
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	05 Apr 2021 01:17:38
User entered 'Oral (ORAL)'	Sarah Wiatrek (b) (4) (b) (4)	11 Mar 2021 14:48:24

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

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)	01 May 2021 07:45:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:39
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered empty.	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	11 Mar 2021 14:48:24

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:08:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:39
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered '05 Feb 2021'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	11 Mar 2021 14:48:24

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:39
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	05 Apr 2021 01:17:38
User entered '0'	Sarah Wiatrek (b) (4) (b) (4)	11 Mar 2021 14:48:24

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:39
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'No (N)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	11 Mar 2021 14:48:24

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

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)	01 May 2021 07:45:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:39
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered '13 Feb 2021'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	11 Mar 2021 14:48:24

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

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)	01 May 2021 07:45:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:07:39
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:38
User entered 'No (N)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	11 Mar 2021 14:48:24

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:05
User entered '1'	System	11 Mar 2021 14:48:24

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:05
User entered '1'	System	11 Mar 2021 14:48:24

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:45:05
User entered '804 (804)'	System	11 Mar 2021 14:48:24

US3632127

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)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:14:20
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	05 Apr 2021 01:17:38
User entered 'No (N)'	Christina Bacher (b) (4) (b) (4)	20 Nov 2020 14:59:38

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:10:23
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'USA-US120-2020-MRNA-1273-P301000004'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:10:31
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Yes (Y)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

Death

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:11:14
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'No (N)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:11:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Yes (Y)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

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.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:11:19
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'No (N)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

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.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:06
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'No (N)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:17:04
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'No (N)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:17:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Yes (Y)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:18:21
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Colleen'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:18:23
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Kelley'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:18:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'GA'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:18:39
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:58:19
User entered 'US'	System	11 Nov 2020 20:57:25

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

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	20 Nov 2020 15:43:00
User entered '2'	System	16 Nov 2020 14:58:35
User entered '1'	System	11 Nov 2020 20:57:25

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:10:23
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'USA-US120-2020-MRNA-1273-P301000004'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:10:31
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Yes (Y)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

Death

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:11:14
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'No (N)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:11:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Yes (Y)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

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.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:11:19
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'No (N)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

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.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:06
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'No (N)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:17:04
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'No (N)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:17:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Yes (Y)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:18:21
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Colleen'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:18:23
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Kelley'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:18:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'GA'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:18:39
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:58:19
User entered 'US'	System	11 Nov 2020 20:57:25

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

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	20 Nov 2020 15:43:00
User entered '2'	System	16 Nov 2020 14:58:35
User entered '1'	System	11 Nov 2020 20:57:25

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

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.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:18:44
User entered '11/Nov/2020 20:57'	System	11 Nov 2020 20:57:25

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

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.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:18:45
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:58:19
User entered '1'	(b) (4), (b) (6)	11 Nov 2020 20:57:25

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:10:23
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'USA-US120-2020-MRNA-1273-P301000004'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:10:31
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Yes (Y)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

Death

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:11:14
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'No (N)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:11:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Yes (Y)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

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.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:11:19
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'No (N)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

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.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:06
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'No (N)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:17:04
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'No (N)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:17:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Yes (Y)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:18:21
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Colleen'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:18:23
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Kelley'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:18:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'GA'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:18:39
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:58:19
User entered 'US'	System	11 Nov 2020 20:57:25

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

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	20 Nov 2020 15:43:00
User entered '2'	System	16 Nov 2020 14:58:35
User entered '1'	System	11 Nov 2020 20:57:25

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

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.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:18:53
User entered '16/Nov/2020 09:58'	System	16 Nov 2020 14:58:35

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

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.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 15:42:46
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:18:55
User entered '1'	(b) (4), (b) (6)	16 Nov 2020 14:58:35

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:10:23
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'USA-US120-2020-MRNA-1273-P301000004'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:10:31
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Yes (Y)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

Death

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:11:14
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'No (N)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:11:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Yes (Y)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

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.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:11:19
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'No (N)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

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.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:06
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'No (N)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:17:04
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'No (N)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:17:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Yes (Y)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:18:21
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Colleen'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:18:23
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Kelley'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:18:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'GA'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:18:39
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:58:19
User entered 'US'	System	11 Nov 2020 20:57:25

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

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	20 Nov 2020 15:43:00
User entered '2'	System	16 Nov 2020 14:58:35
User entered '1'	System	11 Nov 2020 20:57:25

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

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)	06 Apr 2021 19:06:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
User entered '20/Nov/2020 10:42'	(b) (4) System	20 Nov 2020 15:43:00

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

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)	06 Apr 2021 19:06:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:17:45
User entered 'I'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 15:43:00